DEPARTMENT OF LABOR AND INDUSTRY

CHAPTER 174

BOARD OF PHARMACY

Subchapter 1

Organizational Rules

Subchapter 2

Procedural Rules

Subchapter 3

Definitions

Subchapter 4

General Provisions

DEPARTMENT OF LABOR AND INDUSTRY

Subchapter 5

Licensing

PHARMACY

Subchapter 6

Internship Regulations

PHARMACY

Subchapter 7

Pharmacy Technicians

Subchapter 8

Pharmacies

PHARMACY

Subchapter 10

Out-of-State Mail Service Pharmacies

DEPARTMENT OF LABOR AND INDUSTRY

Subchapter 11

Institutional Pharmacies

PHARMACY

Subchapter 12

Wholesale Drug Distributors Licensing

Subchapter 13

Telepharmacy

DEPARTMENT OF LABOR AND INDUSTRY

Subchapter 14

Dangerous Drug Act

Subchapters 15 through 20 reserved

Subchapter 21

Renewals and Continuing Education

Subchapter 22 reserved

Subchapter 23

Unprofessional Conduct

Subchapter 24

Disciplinary/Complaint Procedures

Sub-Chapter 1

Organizational Rules

24.174.101 BOARD ORGANIZATION (1) The board of pharmacy hereby adopts and incorporates the organizational rules of the department of labor and industry as listed in chapter 1 of this title. (History: 37-7-201, MCA; IMP, 2-4-201, MCA; Eff. 12/31/72; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904.)

Sub-Chapter 2

Procedural Rules

24.174.201 PROCEDURAL RULES (1) The board of pharmacy hereby adopts and incorporates the procedural rules of the department of labor and industry as listed in chapter 2 of this title. (History: 37-7-201, MCA; IMP, 2-4-201, MCA; Eff. 12/31/72; AMD, Eff. 11/4/76; TRANS, from Dept. of Prof & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.202 PUBLIC PARTICIPATION RULES (1) The board of pharmacy hereby adopts and incorporates by this reference the public participation rules of the department of commerce as listed in chapter 2 of this title. (History: 37-7-201, MCA; IMP, 2-3-103, MCA; Eff. 12/31/72; AMD, Eff. 11/4/76; TRANS, from Dept. of Prof & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904.)

Subchapter 3

Definitions

24.174.301 DEFINITIONS In addition to the terms defined in 37-7-101, MCA, the following definitions apply to the rules in this chapter.

(1) "Biological safety cabinet" means a contained unit suitable for the preparation of low to moderate risk agents and where there is a need for protection of the product, personnel, and environment according to National Sanitation Foundation Standard 49.

(2) "Class 100 environment" means an atmospheric environment which contains fewer than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209E.

(3) "Clean room" means a room in which the concentration of airborne particles is controlled.

(4) "Cytotoxic" means a pharmaceutical agent capable of killing living cells.

(5) "DEA" means the Drug Enforcement Administration of the United States Department of Justice.

(6) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(7) "Device" is defined in 37-2-101, MCA and is required under federal law to bear the label "Caution: Federal law requires dispensing by or on the order of a physician" or "Rx only."

(8) "Drug order" means a written or electronic order issued by an authorized practitioner, or a verbal order promptly reduced to writing, for the compounding and dispensing of a drug or device to be administered to patients within the facility.

(9) "Drug room" means a secure, lockable temperature-controlled location within a facility that does not have an institutional pharmacy and which contains drugs and devices for administration to patients within the facility pursuant to a valid drug order.

(10) "Electronic signature" means a confidential personalized method of affixing a signature to an electronic document that will guarantee the identity of the prescriber.

(11) "Emergency drug cart" or "crash cart" means a secure lockable cart containing drugs and devices necessary to meet the immediate therapeutic needs of inpatients or outpatients and which cannot be obtained from any other authorized source in sufficient time to prevent risk or harm or death to patients.

(12) "Emergency kits" are sealed kits containing those drugs which may be required to meet the immediate therapeutic needs of patients within an institution not having an in-house pharmacy, and which would not be available from any other authorized source in sufficient time to prevent risk or harm or death to patients.

(13) "Facility" means an outpatient center for surgical services, a hospital and/or long term care facility, or a home infusion facility.

(14) "Floor stock" means prescription drugs not labeled for a specific patient which are maintained at a nursing station or other hospital department other than the pharmacy, and which are administered to patients within the facility pursuant to a valid drug order. Floor stock shall be maintained in a secure manner pursuant to written policies and procedures, which shall include but not be limited to automated dispensing devices.

(15) "Formulary" means a current compilation of pharmaceuticals authorized for use within the institution by representatives of the medical staff and pharmacy department.

(16) "Home infusion facility" means a facility where parenteral solutions are compounded and distributed to outpatients for home infusion pursuant to a valid prescription or drug order.

(17) "Institutional pharmacy" means that physical portion of an institutional facility where drugs, devices, and other material used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, and distributed to other health care professionals for administration to patients within or outside the facility, and pharmaceutical care is provided.

(18) "Labeling" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and Montana law or rule.

(19) "Long term care facility" has the same meaning as provided in 50-5-101, MCA, and means a facility or part of a facility that provides skilled nursing care, residential care, intermediate nursing care, or intermediate developmental disability care to a total of two or more individuals or that provides personal care.

(20) "Medical gas" means any gaseous substance that meets medical purity standards and has application in a medical environment. Examples of medical gases include but are not limited to oxygen, carbon dioxide, nitrous oxide, cyclopropane, helium, nitrogen, and air.

(21) "Medical gas distributor" is a person engaged in the manufacture, processing, packaging, labeling, or distribution of a medical gas to a person other than a consumer or patient.

(22) "Medical gas supplier" is a person engaged in selling, transferring, or delivering to a patient or a patient's agent one or more doses of medical gas in the manufacturer's or distributor's original container for subsequent use by the patient.

(23) "Night cabinet" means a secure locked cabinet or other enclosure located outside the pharmacy, containing drugs which authorized personnel may access in the absence of a pharmacist.

(24) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for consumer use in accordance with the requirements of the laws and rules of Montana and the federal government.

(25) "Outpatient center for surgical services" is as defined at 50-5-101, MCA.

(26) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of skin.

(27) "Pharmacist-in-charge" means a pharmacist licensed in Montana who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and who is personally in full and actual charge of such pharmacy.

(28) "Provisional pharmacy" means a pharmacy licensed by the Montana Board of Pharmacy and includes but is not limited to federally qualified health centers as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

(29) "Qualified patients" mean patients who are uninsured, indigent, or have insufficient funds to obtain needed prescription drugs.

(30) "Remote pharmacy" means a licensed pharmacy at which prescriptions may be filled or transmitted to a central hub pharmacy for filling and subsequent delivery to the remote site or the patient's home. Patient counseling by a pharmacist may occur at this site.

(31) "Remote telepharmacy dispensing machine site" means a licensed site containing prescription inventory which is secured in an automated dispensing device and which has access to its parent pharmacy and registered pharmacists via computer, video, and audio link at all times during business hours.

(32) "Remote telepharmacy site" means a licensed site staffed by a registered pharmacy technician with access to its parent pharmacy and registered pharmacists via computer, video, and audio link at all times during business hours.

(33) "Satellite pharmacy" means a specialized inpatient pharmacy staffed by a pharmacist which is adjacent to or near the department served and is connected via computer to the central institutional pharmacy.

(34) "Security" or "secure system" means a system to maintain the confidentiality and integrity of patient records which are being sent electronically.

(35) "Sterile pharmaceutical" means any dosage form containing no viable microorganisms, including but not limited to parenterals and ophthalmics.

(36) "Verification audit" means a comparison and verification of written patient orders with medications removed for that patient. (History: 37-1-131, 37-7-201, 50-32-314, MCA; IMP, 37-7-102, 37-7-201, 37-7-301, 37-7-321, 37-7-406, 37-7-603, 37-7-604, 37-7-605, 50-32-314, MCA; Eff. 6/9/61; AMD, Eff. 2/27/72; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1993 MAR p. 293, Eff. 2/26/93; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2008 MAR p. 1151, Eff. 6/13/08.)

24.174.302 HOSPITAL/HEALTH CARE FACILITY DEFINITIONS (REPEALED) (History: 37-7-201, MCA; IMP, 37-7-321, MCA; NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/3/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2000 MAR p. 460, Eff. 2/11/00; AMD, 2001 MAR p. 783, Eff. 5/11/01; TRANS, from Commerce, 2002 MAR p. 904; REP, 2002 MAR p. 3605, Eff. 12/27/02.)

24.174.303 INTERNSHIP PROGRAM DEFINITIONS (1) "Approved program" means that time credited toward the training period which begins from the date of intern registration and continues under the requirements of the approved program.

(2) "Approved training area" means a place for instructing an intern for licensure subject to requirements of the board.

(3) "Computed time" means that time credited toward the training period which begins from the date of intern registration and continues under the requirements of the approved program.

(4) "Intern" means a qualified [under ARM 24.174.602] pharmacy student, or a graduate from an accredited school of pharmacy, and registered in an approved program of supervised training.

(5) "Intern certificate of registration" means that certificate furnished by the board upon approval of the intern application form, received from the intern applicant.

(6) "Internship period" means 1500 hours of practical experience in an approved pharmacy, hospital, or other facility. The intern must acquire a minimum of 20 hours experience per calendar week and may acquire a maximum of 48 hours experience per calendar week. The student may acquire up to 1500 hours concurrently with school attendance in approved courses, introductory pharmacy practice experience, and advanced pharmacy practice experience, or demonstration projects in the Pharm.D. program.

(7) "Preceptor" means a pharmacist or other approved individual who meets those requirements for the supervision and training of an intern.

(8) "Reporting period" means at the completion of internship or introductory pharmacy practice experience in a given site or after 500 hours, whichever comes first, or at the completion of advanced pharmacy practice experience.

(9) "Supervision" means that all drug distribution or dispensing activities shall be performed by the intern under the direction of a registered pharmacist and that the preceptor shall have overall responsibility for the required training of the intern. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1997 MAR p. 163, Eff. 11/18/97; AMD, 2001 MAR p. 783, Eff. 5/11/01; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

Subchapter 4

General Provisions

24.174.401 FEE SCHEDULE

(1) Application for licensure transfer	$300
(2) Original registration for pharmacist	120
(3) Pharmacist annual renewal fee	110
(4) Certified pharmacy original certification (includes original, change in location, and change in ownership)	400
(5) Certified pharmacy annual renewal fee	250
(6) Class IV facility, certified pharmacy license, (original and renewal)	75
(7) Intern registration	80
(8) Montana NAPLEX examination processing fee (a separate exam fee is paid directly to NABP)	35
(9) Montana multistate pharmacy jurisprudence examination (MPJE) exam fee (a separate exam fee is paid directly to NABP)	25
(10) Utilization plan approval fee	200
(11) Annual utilization plan renewal fee	100
(12) Pharmacy technician and technician-in-training registration fee	60
(13) Pharmacy technician renewal fee	50
(14) Wholesale drug distributor license	400
(15) Annual wholesale drug distributor renewal	400
(16) Out-of-state mail service pharmacy/telepharmacy initial license	400
(17) Out-of-state mail service pharmacy/telepharmacy renewal	400
(18) Certification of grades/transfer of internship hours	20
(19) Inactive pharmacist annual renewal fee	25
(20) Outpatient center for surgical services (original or renewal)	75

(21) Additional standardized fees are specified in ARM 24.101.403. (History: 37-1-134, 37-7-201, 50-32-314, MCA; IMP, 37-1-134, 37-7-201, 37-7-302, 37-7-321, 37-7-604, 37-7-605, 37-7-703, 50-32-314, MCA; NEW, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 1279, Eff. 4/25/80; AMD, 1981 MAR p. 625, Eff. 6/26/81; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1984 MAR p. 1567, Eff. 10/26/84; AMD, 1987 MAR p. 478, Eff. 5/1/87; AMD, 1988 MAR p. 271, Eff. 2/12/88; AMD, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 1992 MAR p. 1754, Eff. 8/14/92; AMD, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1995 MAR p. 2689, Eff. 12/8/95; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 1998 MAR p. 3103, Eff. 11/20/98; RESCIND, (CI-75), 1998 MAR p. 3200, Eff. 12/4/98; AMD, 1999 MAR p. 1124, Eff. 5/21/99; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2006 MAR p. 1583, Eff. 7/1/06; AMD, 2006 MAR p. 2134, Eff. 9/22/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2008 MAR p. 631, Eff. 4/11/08; AMD, 2008 MAR p. 1151, Eff. 6/13/08.)

24.174.402 DANGEROUS DRUG FEE SCHEDULE (1) The fees to be assessed for registration to manufacture, distribute, dispense, conduct research, or analyze, a dangerous drug shall be assessed according to the following schedule:

REGISTRATION	ANNUAL FEE
(a) manufacture	$100
(b) distribute	100
(c) dispense	
(i) pharmacies	75
(ii) ambulatory surgical facilities	75
(d) conduct research or analyze	100

(History: 37-1-134, 37-7-201, 50-32-103, 50-32-314, MCA; IMP, 37-1-134, 37-7-201, 37-7-321, 50-32-103, 50-32-314, MCA; NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1987 MAR p. 478, Eff. 5/1/87; AMD, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 2134, Eff. 9/22/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.403 CHANGE IN ADDRESS AND/OR EMPLOYMENT (1) All licensees shall notify the board in writing within ten days of any change in employment and/or any change of business or personal address. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.404 FEE ABATEMENT (1) The Board of Pharmacy adopts and incorporates by reference the fee abatement rule of the Department of Labor and Industry found at ARM 24.101.301. (History: 37-1-131, MCA; IMP, 17-2-302, 17-2-303, 37-1-134, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06.)

Rules 24.174.405 through 24.174.410 reserved

24.174.411 PHARMACIST MEAL/REST BREAKS (1) In any pharmacy staffed by a single pharmacist, the pharmacist shall take a meal/rest break for a period of up to 30 minutes per shift without closing the pharmacy and removing support personnel, provided the pharmacist reasonably believes that the security of prescription drugs will be maintained in the pharmacist's absence.

(2) The time of the meal/rest break will be conspicuously posted in clear view of patients approaching the prescription area.

(3) In the pharmacist’s absence a sign indicating that no pharmacist is on duty will be conspicuously displayed in clear view of patients approaching the prescription area.

(4) The pharmacist will remain on the premises if the prescription area is to remain open, and be available for emergencies.

(5) When authorized by the pharmacist, only registered technicians directly involved in the process of filling prescriptions may remain in the prescription department to perform nondiscretionary duties as delineated by the pharmacist.

(6) Upon returning, the pharmacist shall review any work performed in the pharmacist’s absence.

(7) In the pharmacist's absence there may be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor may counseling be provided.

(8) At the discretion of the pharmacist, previously checked medication refills may be handed to patients or their agents by registered technicians in the pharmacist's absence, and the technicians must offer the patient counseling by the pharmacist. If the patient desires counseling, the patient may wait for the pharmacist to return or may leave a telephone number for the pharmacist to call upon return.

(9) Telephoned new prescriptions must not be accepted by support personnel in the pharmacist's absence.

(10) New hardcopy prescriptions may be accepted and processed by registered technicians in the pharmacist's absence. These prescriptions may not be dispensed until the pharmacist has performed prospective drug review and completed the final check.

(11) If two or more pharmacists are on duty, the pharmacists shall stagger their breaks so that the prescription department is not left without a pharmacist on duty.

(12) The pharmacist-in-charge shall develop written policies and procedures for operation of the prescription department in the temporary absence of the pharmacist. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.)

NEXT PAGE IS 24-19539

Subchapter 5

Licensing

24.174.501 EXAMINATION FOR LICENSURE AS A REGISTERED PHARMACIST (1) The board has selected the National Association of Boards of Pharmacy (NABP) licensure examination (NAPLEX) to be administered to candidates for licensure in Montana. The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. A score of 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination after a 90-day waiting period from the date of the exam.

(2) In addition the NABP shall administer a multistate pharmacy jurisprudence examination (MPJE). This examination shall be prepared to measure the competence of the applicant regarding the statutes and rules governing the practice of pharmacy. A score of not less than 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination after a 30-day waiting period from the date of the exam.

(3) Pharmacy graduates from outside the 50 states, the District of Columbia, or Puerto Rico, who seek certification of educational equivalency in order to sit for the North American pharmacist licensure examination must also complete the following:

(a) a successful interview before the Board of Pharmacy or its designee;

(b) the Foreign Pharmacy Graduate Equivalency Examination (FPGEE);

(c) 1500 hours of internship in the United States;

(d) the Test of Spoken English (TSE); and one of the following:

(i) the computer-based Test of English as a Foreign Language (TOEFL);

(ii) the paper-based TOEFL;

(iii) the internet-based TOEFL.

(4) NABP minimum passing scores must be achieved on all tests and examinations. (History: 37-1-131, 37-7-201, MCA; IMP, 37-1-131, 37-7-201, 37-7-302, MCA; NEW, Eff. 11/25/77; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1986 MAR p. 945, Eff. 5/30/86; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.502 TRANSFER OF LICENSE FROM ANOTHER STATE

(1) Applicants seeking a license on the basis of having taken the NAPLEX examination and then issued a license by another state shall submit the following information to the board:

(a) NABP transfer of licensure application;

(b) proof of passing examination score on the NAPLEX examination;

(c) verification of current licensure in good standing from all other states where licensed; and

(d) appropriate fees.

(2) An applicant who has been registered as a pharmacist by examination in another state but who has not taken the NAPLEX examination shall appear before the board for consideration of transfer of licensure and submit the following information to the board:

(a) transfer of licensure application;

(b) proof of passing examination score;

(c) verification of current licensure in good standing from all other states where licensed; and

(d) appropriate fees.

(3) In addition to the requirements in (1) and (2), the applicant will be required to pass the MPJE, to measure the competence of the applicant regarding the statutes and rules governing the practice of pharmacy. A score of not less than 75 shall be a passing score for this examination.

(4) The applicant has one year from the date of the NABP application in which to complete the licensure process. An applicant who does not obtain a license in one year will be required to file a new application and pay the appropriate fees. (History: 37-7-201, MCA; IMP, 37-1-304, MCA; NEW, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS (1) A pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs in order to administer and/or prescribe vaccinations.

(2) A pharmacist may administer vaccines to persons 18 years of age or older provided that:

(a) the pharmacist has successfully completed an accredited course of training provided by the Centers for Disease Control and Prevention (CDC), the American Council on Pharmaceutical Education or other authority approved by the board;

(b) the pharmacist holds a current basic cardiopulmonary resuscitation certification issued by the American Heart Association, the American Red Cross or other recognized provider;

(c) the vaccines are administered in accordance with an established protocol that includes emergency measures; and

(d) the pharmacist has a current copy of or on-site access to the Centers for Disease Control and Prevention reference "Epidemiology and Prevention of Vaccine-Preventable Diseases."

(3) The pharmacist must give the appropriate vaccine information statement to the patient or the patient's legal representative with each dose of vaccine covered by these forms and counsel the patient accordingly.

(4) The pharmacist must maintain written policies and procedures for disposal of used or contaminated supplies.

(5) The pharmacist must report any adverse events to the primary care provider identified by the patient and to the CDC.

(6) A pharmacist administering any vaccine shall maintain the following information in the patient's medical records for a period of at least three years:

(a) the name, address, allergies, and date of birth of the patient;

(b) the date of administration;

(c) the name, manufacturer, dose, lot number, and expiration date of the vaccine;

(d) the vaccine information statement provided;

(e) the site and route of administration;

(f) the name and address of the patient's primary health care provider;

(g) the date on which the vaccination information was reported to the patient's primary health care provider under the provisions of the National Vaccine Injury Compensation Program;

(h) the name of the administering pharmacist; and

(i) any adverse events encountered.

(7) The authority of a pharmacist to administer immunizations may not be delegated; however, an immunization-certified intern may immunize under the direct supervision of a pharmacist qualified under this chapter.

(8) The pharmacist must provide a certified true copy of the immunization certificate and CPR certification to the board for initial endorsement on their pharmacy license.

(9) In order to maintain the immunization endorsement on their pharmacy license, an immunization certified pharmacist must:

(a) maintain current CPR certification;

(b) participate in a minimum of two hours of continuing education on immunizations or vaccine-preventable diseases every year. The continuing education must be American Council on Pharmaceutical Education (ACPE), Continuing Medical Education (CME), or Continuing Education Advisory Council (CEAC) approved; and

(c) maintain competency in vaccine administration technique by:

(i) professionally administering vaccinations to humans in the previous 12 months; or

(ii) having a Montana licensed health care provider authorized to prescribe or administer vaccines or an immunization-certified pharmacist witness and validate the pharmacist's vaccine administration technique every year.

(10) The board shall randomly select renewal notice forms of immunization-certified pharmacists for audit and verification of the requirements listed in this rule. (History: 37-7-101, 37-7-201, MCA; IMP, 37-7-101, 37-7-201, MCA; NEW, 2002 MAR p. 794, Eff. 2/1/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.504 INACTIVE LICENSE (1) A pharmacist may obtain an inactive license through a written request to the board, if the pharmacist holds an active Montana pharmacist license in good standing, and will not practice in Montana for the period of inactive licensure.

(2) A pharmacist with an inactive status of three years or less, whether or not the pharmacist has been in practice in another state, wishing to return to active status in Montana shall:

(a) submit a written request for status change to the board;

(b) pay either:

(i) the difference between the current inactive and active license renewal fees if the change occurs between renewal periods; or

(ii) the full active license renewal fee if the change occurs during the regular renewal period;

(c) certify that:

(i) no disciplinary action has been taken by any state or federal jurisdiction which would prevent or restrict the pharmacist's practice of the profession; and

(ii) the pharmacist has not surrendered any credential or privilege in the practice of the profession in lieu of or to avoid formal action;

(d) submit verification of active practice from the state(s) in which practice occurred; and

(e) provide proof that continuing education requirements for the period of inactive licensure have been satisfied.

(3) A pharmacist with an inactive status of three to five years, who has not been in active practice in another U.S. state, wishing to return to active status in Montana shall:

(a) comply with the requirements of (2);

(b) complete an appropriate internship of 300 hours or take and pass the North American Pharmacist Licensure Examination (NAPLEX); and

(c) take and pass the Multistate Pharmacy Jurisprudence Examination (MPJE) for the state of Montana.

(4) A pharmacist with an inactive status of five years or more, who has not been in active practice in another U.S. state, wishing to return to active status in Montana shall:

(a) comply with the requirements of (2);

(b) complete an appropriate internship of 300 hours;

(c) take and pass the NAPLEX; and

(d) take and pass the MPJE for the state of Montana.

(5) A pharmacist with an inactive status for more than three years, who has been in active practice in another U.S. state, wishing to return to active status in Montana shall:

(a) comply with the requirements of (2); and

(b) take and pass the MPJE for the state of Montana. (History: 37-1-319, 37-7-201, MCA; IMP, 37-1-319, 37-7-201, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06.)

Rules 24.174.505 through 24.174.509 reserved

NEXT PAGE IS 24-19547

24.174.510 PRESCRIPTION REQUIREMENTS (1) Prescriptions [or drug orders] shall include, but not be limited to:

(a) date of issuance;

(b) name and address of patient [or patient location if an institution];

(c) name and address of prescriber [if not a staff physician of institution];

(d) DEA number of prescriber in the case of controlled substances;

(e) name, strength, dosage form and quantity [or stop date, and route of administration] of drug prescribed;

(f) refills authorized;

(g) directions of use for patient.

(Note: Information presented in brackets [ ] represents institutional pharmacy requirements.) (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 1985 MAR p. 1017, Eff. 7/26/85; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.511 LABELING FOR PRESCRIPTIONS (1) On prescription drugs, the label shall contain the name, address and phone number of the dispenser, name of prescriber, name of patient, name and strength of the drug, directions for use and date of filling.

(2) The prescription label must be securely attached to the outside of the container in which the prescription is dispensed. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 7/19/68; AMD, 1978 MAR p. 393, Eff. 3/25/78; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2001 MAR p. 783, Eff. 5/11/01; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.512 RECORDS OF DISPENSING (1) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for at least two years and shall include, but not be limited to:

(a) quantity dispensed, if different;

(b) date of dispensing;

(c) serial number [or equivalent if an institution];

(d) the identification of the pharmacist responsible for dispensing;

(e) documentation of satisfaction of state requirements for drug product selection;

(f) records of refills to date.

(Note: Information presented in brackets [ ] represents institutional pharmacy requirements.) (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 1985 MAR p. 1017, Eff. 7/26/85; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.513 COPY OF PRESCRIPTION (1) A pharmacist giving a copy of a prescription, must issue the same on a prescription blank showing the name and address of the pharmacy. It must be an accurate and correct copy and have the original number and date of the prescription on it.

(2) It shall be unlawful for any pharmacist or other person to fill a prescription for a legend drug from a pharmacy-produced copy. (History: 37-7-201, MCA; IMP, 37-7-101, MCA; NEW, Eff. 6/7/66; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.514 TRANSFER OF PRESCRIPTIONS (1) The manual transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(a) the transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(i) write the word 'VOID' on the face of the invalidated prescription,

(ii) record on the reverse of the invalidated prescription the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information,

(iii) record the date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(i) write the word 'TRANSFER' on the face of the transferred prescription,

(ii) provide all information required to be on a prescription pursuant to state and federal laws and regulations and include:

(A) date of issuance of original prescription,

(B) original number of refills authorized on original prescription,

(C) date of original dispensing,

(D) number of valid refills remaining and date of last refill,

(E) pharmacy's name, address and original prescription number from which the prescription information was transferred,

(F) name of transferor pharmacist.

(2) The manual transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only, by following the procedures listed above. In addition:

(a) the transferring pharmacist shall record on the reverse of the invalidated prescription the DEA registration number of the pharmacy to which it was transferred; and

(b) the pharmacist receiving the transferred prescription shall record the DEA registration number of the pharmacy from which the prescription information was transferred.

(3) The electronic transfer of prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(a) the transferring pharmacy shall:

(i) render the prescription void;

(ii) enter the name, address, and DEA number of the receiving pharmacy into the database of the transferring pharmacy;

(iii) inform the receiving pharmacy of:

(A) the date on which the prescription was written;

(B) the original number of refills;

(C) the number of refills remaining; and

(D) the date of the most recent refill; and

(iv) maintain a retrievable audit trail, including the date of transfer and initials or code of the transferring party, for a period of two years; and

(b) the receiving pharmacy shall maintain documentation including:

(i) a notation that the prescription was received by transfer;

(ii) the date on which the prescription was written;

(iii) the original prescription number of the transferred prescription;

(iv) the original number of refills, number of refills remaining, and the date of the most recent refill;

(v) the name, address, and DEA number of the transferring pharmacy;

(vi) all other prescription information required by state and federal laws and regulations;

(vii) a retrievable audit trail, including the date of transfer and initials or code of the receiving party, for a period of two years; and

(viii) a nonfading hard copy record of each prescription drug order transferred.

(4) The electronic transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only, by following the procedures listed above.

(5) Pharmacies accessing a common or shared electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the common or shared prescription file, provided, however, that any such common or shared file shall contain complete records of each prescription drug order and refill dispensed. A hard copy record of each prescription drug order accessed for purposes of refilling shall be generated if necessary and maintained at the refilling pharmacy. An easily retrievable audit trail which documents the location of each filling must be maintained and provisions must be made to assure that the number of authorized refills is not exceeded.

(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:

"NOTICE TO CONSUMERS:

This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies: (list names of all pharmacies which share the prescription information).

By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained this way, please notify the pharmacist-in-charge."

(b) Whenever a consumer objects to their prescription records being made accessible to other pharmacies through the use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy except as provided in (1), (2) and (4) of this rule. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows: "I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file." The pharmacist shall date and co-sign the form and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.

(6) In an emergency, a pharmacy may transfer original prescription drug order information for a noncontrolled substance to a second pharmacy for the purpose of dispensing up to seven days supply without voiding the original prescription drug order.

(7) Both the original and transferred prescription must be maintained for a period of at least two years from the date of last refill.

(8) Pharmacies utilizing automated data processing systems must satisfy all information requirements of the manual mode for all prescription transferral and be certain that their system can void the original prescription once it is transferred, yet maintain the information on file. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 1985 MAR p. 1017, Eff. 7/26/85; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

Rules 24.174.515 through 24.174.519 reserved

24.174.520 PRESCRIPTION REQUIRED FOR SCHEDULE V (1) All products which are presently defined as exempt narcotics (Schedule V) of the Comprehensive Controlled Substances Act, Public Law (91-513) shall require a prescription from one with the authority to prescribe. (History: 37-7-201, MCA; IMP, 37-7-102, 37-7-201, MCA; NEW, Eff. 9/16/71; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.521 RETURNED PRESCRIPTION (1) In the best interest of, and for the safety and protection of public health and the pharmacy, no pharmacist shall place in stock for reuse or resale the contents of any prescription, which has been returned after leaving the pharmacy except as provided in ARM 24.174.1141. (History: 37-7-201, 37-7-1401, MCA; IMP, 37-7-201, 37-7-1401, MCA; NEW, Eff. 6/12/57; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.522 ALTERNATE DELIVERY OF PRESCRIPTIONS (1) Under the provisions of 37-7-301, MCA, it shall be deemed a violation of the pharmacy law for any person or corporation holding a pharmacy license to participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by or delivered to any store, shop or any other establishment not licensed by the board as a "pharmacy".

(a) Nothing in this rule shall prohibit a licensed pharmacy from picking up prescriptions or delivering prescriptions at the office or home of the prescriber, and at the residence of the patient or at the hospital in which a patient is confined, by means of an employee or a common carrier.

(b) Nothing in this rule shall prohibit a registered pharmacist from installing an appropriate secure device as an alternate delivery system, when the pharmacy is closed. The system and counseling methods must have the prior approval of the board or its designee. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-301, MCA; NEW, Eff. 9/24/61; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.523 TRANSMISSION OF PRESCRIPTIONS BY ELECTRONIC MEANS (1) A pharmacist may dispense directly any legend drug which requires a prescription to dispense (except as provided in (2) and (3) below for Schedule II, III, IV and V controlled substances), only pursuant to either a written prescription signed by a practitioner or a prescription transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means or pursuant to an oral prescription made by an individual practitioner and promptly reduced to hard copy by the pharmacist containing all information required. The prescription shall be maintained in accordance with ARM 24.174.512.

(2) A pharmacist may dispense directly a controlled substance in Schedule II, which is a prescription drug as determined by the Federal Food, Drug and Cosmetic Act, only pursuant to a written prescription signed by the practitioner. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by electronic means, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. The original prescription shall be maintained in accordance with ARM 24.174.512.

(a) A signed prescription for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the home infusion pharmacy by electronic means. The electronic transmission serves as the original written prescription for the purpose of this rule and it shall be maintained in accordance with ARM 24.174.512.

(b) A signed prescription for a Schedule II substance for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by electronic means. The electronic transmission serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with ARM 24.174.512.

(c) A signed prescription for a Schedule II substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII of the Social Security Act or a hospice program which is licensed by the state of Montana may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by electronic means. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The electronic transmission serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with ARM 24.174.512.

(3) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV or V which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to either a written prescription signed by a practitioner or a copy of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means or pursuant to an oral prescription made by an individual practitioner and promptly reduced to hard copy by the pharmacist containing all information required. The prescription shall be maintained in accordance with ARM 24.174.512.

(4) Prescriptions may be transmitted electronically directly from an authorized prescriber or his/her authorized agent to the pharmacy of the patient's choice without alteration by any other party, providing the following requirements are met:

(a) Both prescriber and pharmacist must have a secure (encrypted or encoded) system for electronic transmission from computer to computer that ensures patient confidentiality;

(b) The receiving electronic device shall be located within the pharmacy department to ensure security and confidentiality;

(c) An electronically transmitted prescription shall contain all information required by state and federal law, including the date and time of transmission, the prescriber's telephone number for verbal confirmation and the name of the prescriber's agent transmitting the order, if other than the prescriber;

(d) The prescriber's electronic signature or other secure (encrypted or encoded) method of validation shall be provided with the electronically transmitted order. Faxed prescription orders shall contain the identifying number of the sending fax machine;

(e) A printed, nonfading copy of an electronically transcribed prescription will be maintained in the pharmacy for a period of two years;

(f) The prescription shall be marked "electronically transmitted prescription" or be otherwise identified for easy retrieval;

(g) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice;

(h) The pharmacist is responsible for assuring the validity of the electronically transmitted prescription;

(i) A pharmacist or pharmacy shall not enter into any agreement to provide or receive a computer or computer modem, personal digital assistant, facsimile machine, or any other electronic device which would adversely affect a patient's freedom to select the pharmacy of the patient’s choice; and

(j) A pharmacist or pharmacy shall not provide a computer or computer modem, personal digital assistant, facsimile machine, or any other electronic device to a prescriber or health care facility for the purpose of providing an incentive to refer patients to a particular pharmacy.

(5) Two or more pharmacies sharing common electronic files to maintain dispensing information are not required to transfer prescription information between these pharmacies, providing all common electronic files maintain complete and accurate records of each prescription and refill dispensed, and the total number of refills authorized is not exceeded.

(a) Any pharmacy sharing a common electronic file for prescription records shall post the following notice in readily readable form in a conspicuous place within the pharmacy:

"This pharmacy maintains its prescription information in a secure electronic file that is shared by the following pharmacies: (list names of pharmacies which share the prescription information). If refills are authorized, your prescriptions may be refilled at any of the above locations. If you do not want your prescriptions to be maintained in this way, please notify the pharmacist at the time of filling."

(b) Pharmacies sharing common electronic files will have policies and procedures in place for handling these exceptions. (History: 37-7-201, 50-32-103, MCA; IMP, 37-7-102, 37-7-201, 50-32-208, MCA; NEW, 1995 MAR p. 2689, Eff. 12/8/95; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.524 COLLABORATIVE PRACTICE AGREEMENT REQUIREMENTS

(1) Prior to initially engaging in collaborative practice, a pharmacist must provide the board with an executed written and electronic copy of the collaborative practice agreement.

(2) The collaborative practice agreement must include:

(a) the identification and signature of individual practitioner(s) authorized to prescribe drugs and responsible for the delegation of drug therapy management;

(i) the practitioner as defined in 37-2-101, MCA, must be licensed in good standing in Montana; and

(ii) the practitioner must be in active practice in the community in which the collaborating pharmacist practices. A request for an exception to this provision must be in writing and will be decided by the board.

(b) the identification and signature of individual pharmacist(s) authorized to dispense drugs and engage in drug therapy management;

(c) the types of drug therapy management decisions that the pharmacist is allowed to make which may include:

(i) a specific description of the types of diseases and drugs involved, and the type of drug therapy management allowed in each case; and

(ii) a specific description of the procedures and methods, decision criteria and plan the pharmacist is to follow.

(d) a detailed description of the procedures and patient activities the pharmacist is to follow in the course of the protocol, including the method for documenting decisions made and a plan or mechanism for communication, feedback and reporting to the practitioner concerning specific decisions made. Documentation shall be recorded within 24 hours following each intervention and may be recorded on the patient medication record, patient medical chart, or a separate log book. Documentation of drug therapy management must be kept as part of the patient's permanent record and shall be considered confidential information;

(e) a method by which adverse events shall be reported to the practitioner;

(f) a method for the practitioner to monitor clinical outcomes and intercede when necessary;

(g) a provision that allows the practitioner to override protocol agreements when necessary;

(h) a provision that allows either party to cancel the agreement by written notification;

(i) the effective date of the protocol. The duration of each protocol shall not exceed one year;

(j) the annual date by which review, renewal, and revision, if necessary, will be accomplished;

(k) the addresses where records of collaborative practice are maintained; and

(l) the process for obtaining the patient's written consent to the collaborative practice agreement.

(3) Patient records shall be maintained by the pharmacist for a minimum of seven years and may be maintained in an automated system pursuant to ARM 24.174.817.

(4) Collaborative practice agreements approved by an institutional committee such as the pharmacy and therapeutics committee and that will be used solely for inpatients are exempt. (History: 37-7-201, MCA; IMP, 37-7-101, 37-7-201, MCA; NEW, 2002 MAR p. 794, Eff. 2/1/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

Subchapter 6

Internship Regulations

24.174.601 SUMMARY OF OBJECTIVES (1) Internship training, using academic training as a foundation, provides a learning experience in real life situations that will result in a professional who is competent to practice pharmacy and render professional services on their own, without supervision at the time of licensure. The objectives shall be:

(a) a practically, accurately and safely trained intern;

(b) an ethically trained intern; and

(c) a legally trained intern. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.602 INTERNSHIP REQUIREMENTS (1) The experience required to obtain licensure as a pharmacist shall be that instruction period composed of computed time obtained under the supervision of the preceptor in an approved site. An intern may not work alone and assume the responsibility of a registered pharmacist.

(2) Application shall be made on the intern application form prescribed by the board. Registration must be obtained prior to commencing work as an intern.

(3) The intern shall receive instruction in only one approved area and under only one preceptor concurrently, except in unusual and extenuating circumstances approved by the board upon written request.

(4) The intern shall make such reports and certifications as required under the approved program.

(5) The intern is responsible for the knowledge and observation of the extent of the intern's legal liability and legal restrictions applicable under the federal, state, and municipal laws and rules.

(6) The intern shall be responsible for ensuring that the preceptor has proper certification.

(7) The intern is responsible for properly submitting all forms and hour reports under the approved program.

(8) Employment and the intern training periods are not to be interpreted as being the same. An intern may work in excess of the computed time.

(9) Only those students who have completed the first professional year (third year) of the pharmacy curriculum may begin their internship.

(10) The intern shall notify the board of any change of address, employment, or preceptor within ten days.

(11) Intern certificate of registration shall be displayed in the approved training area.

(12) An intern will be allowed six months after taking the NAPLEX examination to complete requirements for licensure. The time may be extended, subject to the approval of the board, if extenuating circumstances prohibit completion in the prescribed time. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.603 OUT-OF-STATE INTERNSHIP REQUIREMENTS (1) Written request by the intern must be made to the board prior to commencing training at an out-of-state site.

(2) The intern must comply with the rules relating to internship and the approved program.

(3) The intern must obtain certification of the training area and the preceptor from the out-of-state's board and must submit the same directly to the Montana Board of Pharmacy. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.604 PRECEPTOR REQUIREMENTS (1) Each pharmacist preceptor shall:

(a) apply for board approval to be a preceptor;

(b) have been actively engaged in:

(i) the practice of pharmacy for two years unless otherwise approved by the board; or

(ii) other approved disciplines;

(c) be engaged in active practice while acting as preceptor;

(d) not have been convicted of violation of any statutes or rules relating to pharmacy within three years prior to application;

(e) be acutely aware of the responsibilities governing professional conduct in this state;

(f) have current knowledge of developments in the profession by exhibiting such attendances, readings, and actions, which conform to the best traditions of pharmacy;

(g) make such reports and certifications as required under the approved program;

(h) notify the board of any change of address or employment within ten days. Change of employment shall serve to suspend preceptor approval until such time as reevaluation is made by the board; and

(i) not be permitted to leave an intern work alone to assume the responsibility of a pharmacist.

(2) The repackaging, labeling, and dispensing of drugs for distribution shall be under the supervision of a registered pharmacist or pharmacist preceptor.

(3) A pharmacist preceptor may only supervise one student in internship or one student in introductory pharmacy practice experience (IPPE) at any time.

(4) A pharmacist preceptor may supervise no more than three persons at one time (including technicians and students) unless an exception is specifically granted by the board.

(5) A pharmacist preceptor may supervise two students at a time if the students are completing an advanced pharmacy practice experience (APPE) through an approved school of pharmacy. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2001 MAR p. 783, Eff. 5/11/01; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.605 FOREIGN INTERN REQUIREMENTS (1) A graduate of a foreign school of pharmacy seeking licensure to practice as a pharmacy intern in the state of Montana shall:

(a) take the Foreign Pharmacy Graduate Equivalency Exam (FPGEE);

(b) take the Test of Spoken English (TSE); and one of the following:

(i) take the computer-based Test of English as a Foreign Language (TOEFL);

(ii) take the paper-based TOEFL; or

(iii) take the internet-based TOEFL;

(c) achieve NABP minimum passing scores on all tests and examinations;

(d) have an internship practice site identified and that practice site must be a licensed pharmacy in good standing with the board; and

(e) have an internship preceptor identified and that preceptor must:

(i) be a licensed pharmacist in good standing with the board; and

(ii) be a registered preceptor in good standing with the board.

(2) The intern and their preceptor must appear before the board.

(3) The intern shall comply with the internship requirements as set forth in ARM 24.174.602.

(4) A graduate of a foreign school of pharmacy must complete 1500 hours of internship in the United States in order to be eligible for pharmacist licensure in Montana. (History: 37-1-131, 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

Rules 24.174.606 through 24.174.610 reserved

24.174.611 APPROVED TRAINING AREAS (1) Approved training areas will include licensed pharmacy settings plus other health care and research settings approved by the board. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.612 REQUIRED FORMS AND REPORTS (1) Forms shall be furnished by the board, the cost of which is included in the application for internship registration.

(a) The "intern application" must be filed by the intern before computed time is credited.

(b) The "internship experience affidavit", provided by the board, must be filed by the intern at the end of the internship experience in a given site or after 500 hours, whichever comes first.

(c) The "evaluation of internship site" must be filed by the intern at the completion of internship or externship experience in a given site or after 500 hours, whichever comes first.

(d) The "clerkship experience affidavit", provided by the board, must be filed by the intern at the end of the academic year. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2000 MAR p. 2005, Eff. 7/28/00; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.613 REVOCATION OR SUSPENSION OF CERTIFICATE (1) An intern certificate may be suspended or revoked by the board for violation of any statute or rule, or failure to comply with the approved program after due notice.

(2) Suspension of an intern from university or college attendance concurrently suspends an intern's certificate of registration. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

Subchapter 7

Pharmacy Technicians

24.174.701 REGISTRATION REQUIREMENTS (1) In order to be registered as a pharmacy technician in this state, the applicant shall:

(a) submit application on a form prescribed by the board;

(b) pay application fees as prescribed by the board; and

(c) submit a copy of proof of certification by PTCB or other board approved certifying entity.

(2) In order to be registered as a technician-in-training in this state, the applicant shall:

(a) apply to the board for a permit on an application supplied by the board;

(b) pay the fee required;

(c) provide the name and address of the pharmacy in which the technician-in-training is employed. A change in place of employment will require submission of updated information within ten working days of the change.

(3) The permit to practice as a technician-in-training shall be valid for a period of 18 months, and may not be renewed. (History: 37-7-201, MCA, IMP, 37-7-201, MCA; NEW, 2002 MAR p. 86, Eff. 1/18/02.)

24.174.702 QUALIFICATIONS OF PHARMACY TECHNICIAN (1) A person who acts as a pharmacy technician under the provisions of a utilization plan must be:

(a) at least 18 years old;

(b) a high school graduate or have attained an equivalent degree;

(c) of good moral character; and

(d) certified by the Pharmacy Technician Certification Board (PTCB) or other board approved certifying entity.

(2) No pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-301, 37-7-307, MCA; NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2001 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.703 USE OF PHARMACY TECHNICIAN (1) A pharmacy technician may not perform tasks which require the exercise of the pharmacist's independent professional judgment, including but not limited to, patient counseling, drug product selection, drug interaction review or drug regimen review.

(2) When a pharmacist is not in the prescription department, there shall be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor shall counseling be provided by the pharmacy technician.

(3) No medication may be released to a patient without review by a registered pharmacist for the accuracy and appropriateness of the prescription drug order.

(4) All technicians and auxiliary staff shall be made visually identifiable by name and job title utilizing letters of 16 point or larger on a name badge. (History: 37-7-201, MCA; IMP, 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA; NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2000 MAR p. 2005, Eff. 7/28/00; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.704 PHARMACY TECHNICIAN TRAINING (1) A supervising pharmacist shall:

(a) provide initial training to a pharmacy technician that relates to the tasks the technician may perform pursuant to the supervising pharmacist's utilization plan; and

(b) prepare and maintain a written record of initial and inservice training for on-site inspection by the board. The record shall contain the following information:

(i) name and signature of the person receiving the training;

(ii) dates of the training;

(iii) general description of the topics covered; and

(iv) name and signature of the person supervising the training.

(2) An initial training program must include on-the-job practical training and didactic education that is commensurate with the tasks and functions a pharmacy technician may perform. A supervising pharmacist must obtain the board's approval of an initial training program prior to undertaking the training of a pharmacy technician pursuant to the program.

(3) Verification of completion of training, by test or otherwise, shall be recorded by the supervising pharmacist, and shall be available for inspection with the training record. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, MCA; NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.705 TASKS AND FUNCTIONS OF PHARMACY TECHNICIAN

(1) Only a registered pharmacy technician may perform the following tasks or functions under the provisions of an approved utilization plan:

(a) remove a stock bottle from the shelf and count or pour the contents into a suitable container. The stock bottle must be quarantined together with the prescription until the supervising pharmacist performs a final check or bar coding or other available technology verifies the bottle contents;

(b) type a prescription label and affix it and auxiliary labels to a prescription bottle, with final review by the registered pharmacist;

(c) enter prescription information into an automated system under the supervision of a pharmacist who must be able to check all entries;

(d) maintain prescription records, including prescription numbers, refill data and other information on the patient profile system;

(e) prepackage unit dose drugs for internal distribution. These prepackage unit dose drugs must be quarantined together with bulk containers until the supervising pharmacist performs a final check and maintains appropriate records.

(f) answer the telephone, properly identify themselves as a technician, accept verbal orders for refill prescriptions from medical practitioners or their designated agents and issue refill requests to the prescriber;

(g) a pharmacy technician may act as agent in charge of the pharmacy to assure its integrity when a registered pharmacist is not physically present, but may not perform any duties which require the exercise of the pharmacist's independent professional judgment. The technician may not be left in charge for more than 30 minutes; and

(h) compounding if a mechanism for verification by the supervising pharmacist exists that includes checking of: the original order; additives; dosages; and clarity of IV solution, where appropriate.

(2) The board reserves the right to evaluate and amend the functions allowable by a pharmacy technician, with final determination in the sole discretion of the board. (History: 37-7-201, MCA; IMP, 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA; NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

Rules 24.174.706 through 24.174.710 reserved

24.174.711 RATIO OF PHARMACY TECHNICIANS TO SUPERVISING PHARMACISTS (1) A registered pharmacist in good standing may supervise the services of no more than three technicians at any time. The 1:3 pharmacist to pharmacy technician ratio may be revised by the board at any time for good cause.

(2) Registered pharmacists in good standing in the state of Montana may supervise a maximum of three registered pharmacy technicians, provided:

(a) in the professional judgment of the pharmacist on duty, the policy and procedures of the pharmacy must allow for safe and accurate filling and labeling of prescriptions;

(b) the policy and procedures shall be reviewed annually. All affected supervising pharmacists and pharmacy technicians must be familiar with the contents and any changes made must be reported to the board; and

(c) a copy of the policy and procedures must be available for inspection by the board compliance officer.

(3) If a pharmacy desires more than three technicians to work under the supervision, direction, and control of one pharmacist, the pharmacy shall obtain the prior written approval of the board. To apply for approval, the pharmacist-in-charge shall submit a pharmacy services plan to the board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to the following:

(a) design and equipment;

(b) information systems;

(c) work flow; and

(d) quality assurance procedures.

(4) The board shall grant approval of a pharmacy service plan only when the board is satisfied that the provision of pharmaceutical care by the pharmacy will be enhanced by the increased use of technicians. An exception may be revoked by the board at any time for good cause.

(5) No pharmacy shall modify a board approved pharmacy service plan without the prior written approval of the board.

(6) Nothing in this rule shall prevent a pharmacy from terminating a service plan upon written notification to the board. (History: 37-7-201, MCA; IMP, 37-7-101, 37-7-201, 37-7-307, 37-7-308, 37-7-309, MCA; NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.712 APPLICATION FOR APPROVAL OF UTILIZATION PLAN (1) A registered pharmacist in good standing in the state of Montana may apply to the board for permission to use the services of a pharmacy technician by submitting to the board:

(a) an application on a form prescribed by the board;

(b) a summary of the utilization plan, to include information showing compliance with all requirements set forth in these rules, plus all other requirements of 37-7-307, 37-7-308, and 37-7-309, MCA, and this chapter;

(c) the appropriate fee for initial approval of the plan;

(d) any changes in the utilization plan, including technician training, must be resubmitted to the board for approval before implementation of the changes by the supervising pharmacist.

(2) Any number of registered pharmacists employed in the same pharmacy may sign as supervising pharmacist of a pharmacy technician on a single utilization plan submitted for approval to the board by that pharmacy.

(3) A registered pharmacist in good standing in the state of Montana may apply to the board to designate that pharmacy as a technician training site for a board-approved academic program curriculum. If the pharmacy training site does not have an approved technician utilization plan in place, the pharmacy may substitute an academic program training plan, assessment criteria and periodic contact plan for board approval, for the purpose of providing on-the-job experience for technician trainees. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-308, 37-7-309, MCA; NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.713 CONTENTS OF TRAINING COURSE (1) A pharmacy technician training course must include instruction in:

(a) orientation to the practice of pharmacy;

(b) pharmacy terminology and basic pharmaceutics;

(c) state and federal laws relating to the practice of pharmacy;

(d) pharmaceutical calculations;

(e) processing prescription drug orders;

(f) telephone procedure and communication including taking refill requests;

(g) pharmaceutical compounding;

(h) intravenous admixture, if applicable; and

(i) use of pharmacy computer systems, if applicable. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, MCA; NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.714 INSPECTION OF UTILIZATION PLAN AND TRAINING RECORD (1) The supervising pharmacist shall make the utilization plan available for inspection by the board during the normal business hours of the pharmacy.

(2) The pharmacy technician shall make their training record available for inspection by the board during the normal business hours of the pharmacy. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-308, MCA; NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.715 TECHNICIAN CHECK TECHNICIAN PROGRAM (1) To participate in a technician check technician (TCT) program an institutional pharmacy within a hospital must meet the following requirements:

(a) the pharmacy must include TCT as a technician duty, submitted to the Board of Pharmacy by the pharmacist-in-charge as part of the technician utilization plan;

(b) develop a site-specific training program tailored to the patient population and medication distribution system;

(c) designate one pharmacist to be responsible for meeting the TCT program training and validation requirements;

(d) staffing must be adequate to support a consistent utilization of the TCT program;

(e) a pharmacist must review all orders against a medication profile containing pertinent clinical information about the patient (allergies, current medication, etc.);

(f) the medication description on the batch fill list must contain the same description as the labeling on the unit dose package;

(g) the drug distribution system must be structured so that at least one additional check of dispensed medications is completed prior to administration;

(h) develop policies and procedures which include a list of the types of work that a technician may check and the types of work that are excluded from being checked by a technician; and

(i) utilize the TCT program as a tool to redirect pharmacists from distributive tasks to cognitive and patient centered activities.

(2) In order to participate in a TCT program a technician must:

(a) be a registered pharmacy intern in good standing with the board with at least three months experience in unit dose filling; or

(b) be a certified pharmacy technician in good standing with the board working full or part time with six months equivalent experience in unit dose filling; and

(c) complete site specific training in the TCT program.

(3) A TCT training program must include:

(a) didactic lecture (or equivalent training with a self-learning packet);

(b) practical sessions (one-on-one training) which consist of observation of a pharmacist checking a unit dose medication batch and/or cart;

(c) initial validation (and revalidation if needed); and

(d) regular quality assurance audits performed quarterly for the first year then every six months thereafter.

(4) Approval from the Board of Pharmacy or designee is required prior to program implementation.

(5) If at any time a technician loses their validation, that individual must not function as a TCT until they are retrained and revalidated.

(6) All TCT program materials should be readily retrievable for review by the board inspector.

(7) Any facility that is not within an institutional pharmacy within a hospital must come before the board. (History: 37-7-201, MCA; IMP, 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

NEXT PAGE IS 24-19649

Subchapter 8

Pharmacies

24.174.801 GENERAL LICENSE REQUIREMENTS (1) The board shall grant a license for the operation of a pharmacy in the state of Montana when it is plainly shown that:

(a) the owner of the pharmacy is a registered pharmacist in good standing in the state of Montana; or

(b) the manager or supervisor of the pharmacy is a registered pharmacist in good standing in the state of Montana and that the pharmacist will be actively and regularly engaged and employed in, and responsible for the management, supervision and operation of such pharmacy.

(2) The license registers the pharmacy to which it is issued and is not transferable. It is issued on the application of the registered pharmacist in charge, and which contains the sworn statement that the pharmacy will be operated in accordance with the provisions of the law.

(3) To operate, maintain, open, or establish more than one pharmacy, separate applications shall be made and separate licenses issued for each. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-321, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.802 NEW PHARMACY (1) Prior to conducting business, a pharmacy must secure a license and be registered with the board. Application for a license to operate a new pharmacy must be reviewed by the board or its designee before the license may be issued.

(2) A corporation or unregistered owner, may secure a license on the affidavit of the registered pharmacist charged with the management and supervision of the pharmacy.

(3) All new pharmacies shall be in compliance with ARM 24.174.814 at the time the pharmacy is opened for business. (History: 37-7-201, MCA; IMP, 37-7-321, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.803 CHANGE IN LOCATION (1) Whenever a pharmacy changes its physical location, including within the existing business location, it shall submit a new schematic or floor plan, for board approval.

(2) Whenever a pharmacy changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The pharmacy shall submit a new license application, including a new schematic and floor plan of the new location, for the board's approval at least 30 days before such change occurs. (History: 37-7-201, MCA; IMP, 37-7-321, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.804 CHANGE IN OWNERSHIP (1) When a pharmacy changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner or owners. The owner shall submit a new license application at least 30 days prior to the change in ownership. The application must be reviewed by the board or its designee before the license may be issued.

(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

(3) The board must be notified in writing when five to 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-321, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.805 CHANGE OF PHARMACIST-IN-CHARGE (1) When the pharmacist-in-charge of a pharmacy leaves the employment of such pharmacy, the pharmacist will be held responsible for the proper notification to the board of such termination of services.

(2) Within 72 hours of termination of services of the pharmacist-in-charge, a new pharmacist-in-charge must be designated and an affidavit filed with the board. The license will then be updated to indicate the name of the new pharmacist-in-charge. (History: 37-7-201, MCA; IMP, 37-7-321, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.806 LICENSES TO BE POSTED (1) The pharmacy license must be posted in a conspicuous place in the pharmacy. (History: 37-7-201, MCA; IMP, 37-7-321, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.807 CLOSURE OF A PHARMACY (1) Upon permanent closure of a pharmacy, the original license becomes void and must be surrendered to the board within ten days.

(2) Whenever a pharmacy permanently closes, the owner shall notify the board of the closing no later than 15 days prior to the anticipated date of closing. The notice shall be submitted in writing and shall include the following information:

(a) the date the pharmacy will close;

(b) the names and addresses of the persons who will have custody of the closing pharmacy's:

(i) prescription files;

(ii) bulk compounding records;

(iii) repackaging records; and

(iv) controlled substance inventory records.

(c) the names and addresses of any persons who will acquire any legend drugs from the closing pharmacy, if known at the time the notice is filed.

(3) No later than 15 days after the pharmacy has closed, the owner shall submit to the board written confirmation that:

(a) all legend drugs have been either:

(i) destroyed; or

(ii) transferred to an authorized person(s), including the names and addresses of the person(s) to whom the legend drugs were transferred.

(b) controlled substances were transferred, including:

(i) names and addresses of the person(s) to whom the substances were transferred;

(ii) the substances transferred;

(iii) the amount of each substance transferred; and

(iv) the date on which the transfer took place.

(c) the DEA registration and all unused DEA 222 forms (order forms) were returned to the DEA;

(d) all pharmacy labels and blank prescriptions which were in the possession of the pharmacy were destroyed; and

(e) all signs and symbols indicating the presence of the pharmacy have been removed. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-321, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

Rules 24.174.808 and 24.174.809 reserved

24.174.810 CLASS I FACILITY (REPEALED) (History: 37-7-201, MCA; IMP, 37-7-201(2), 37-7-321(2), MCA; NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/31/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; REP, 2002 MAR p. 3605, Eff. 12/27/02.)

24.174.811 CLASS II FACILITY (REPEALED) (History: 37-7-201, MCA; IMP, 37-7-201(2), 37-7-321(2), MCA; NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/31/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; REP, 2002 MAR p. 3605, Eff. 12/27/02.)

24.174.812 CLASS III FACILITY (REPEALED) (History: 37-7-201, MCA; IMP, 37-7-201(2), 37-7-321(2), MCA; NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/3/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; REP, 2002 MAR p. 3605, Eff. 12/27/02.)

24.174.813 CLASS IV FACILITY (1) A Class IV facility shall be administered in compliance with the following standards:

(a) that any legend drugs dispensed shall first have been packaged, labeled, and otherwise prepared by a registered pharmacist holding a current license in Montana. The pharmacist is to be recorded with the board and the board shall be notified of any change of the pharmacist in charge.

(i) a legend drug is defined as one that is controlled by federal law and carries the legend "Federal Law Prohibits Dispensing Without a Prescription".

(b) that the registered pharmacist in charge shall provide this service to said facility at regular periods and that these periods be posted at said facility.

(c) that adequate locked storage be provided for all drugs referred to in these rules. Only the pharmacist may have access to the legend drug stock. However, the person in charge, or his or her designee, may obtain a product that has been properly prepared by the pharmacist for delivery to the recipient.

(d) that records for all legend drugs dispensed and to whom be kept at the facility for the purpose of accounting for these drugs. These records would include present stock and all shipments received thereafter.

(e) that these drugs be delivered to the recipient at no cost for the drug.

(f) that the dispensing of drugs by M.D.'s not be restricted except as defined in 37-2-104 and 37-7-103, MCA.

(g) that nothing in these rules authorizes the dispensing of any drugs and devices other than the following:

(i) oral contraceptives; injectable long-term contraceptives; progestational drugs; diaphragms; contraceptive jellies; creams, and foams; IUD's; condoms; vaginal creams, ointments, and suppositories used in the routine treatment of vaginal disorders.

(h) that all nonlegend contraceptive devices and products be dispensed in accordance with the contraceptive drug or device law, Title 45, chapter 8, 45-8-204, MCA.

(i) that each family planning center must apply for a license from the board and submit the required fee for a Class IV facility. This license is to be displayed in a conspicuous place at the facility. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-321, MCA; NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/31/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.814 SECURITY OF PHARMACY (1) Each pharmacist, while on duty, shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of drugs.

(a) A Schedule II controlled substance perpetual inventory shall be maintained and routinely reconciled in all pharmacies.

(2) The pharmacy shall be secured at all times by either a physical barrier with suitable locks and/or an electronic barrier to detect entry by unauthorized persons at any time. Such barrier shall be approved by the board or its designee before being put into use.

(3) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by the rules of the board.

(4) Sections (1) and (2) of this rule shall be effective February 1, 2004. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 794, Eff. 2/1/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

Rules 24.174.815 and 24.174.816 reserved

24.174.817 AUTOMATED RECORD KEEPING SYSTEMS (1) An automated system may be employed for the record keeping system, if the following conditions have been met:

(a) The system shall have the capability of producing legible documents of all original and refilled prescription information. During the course of an on-site inspection the records must be accessible for viewing or printing.

(b) The individual pharmacist responsible for completeness and accuracy of the entries to system must provide documentation of the fact that prescription information entered into the computer is correct. In documenting this information, the pharmacy shall have the option to either:

(i) maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of at least two years after the date of last dispensing; or

(ii) provide a printout of each day's prescription information. That printout shall be verified, dated and signed by the individual pharmacist verifying that the information indicated is correct and then sign this document in the same manner as signing a check or legal document (e.g., J. H. Smith, or John H. Smith). Such printout must be maintained at least two years from the date of last dispensing.

(c) An auxiliary recordkeeping system shall be established for the documentation of refills if the automated system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When this automated system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated system within 96 hours. However, nothing in this section shall preclude the pharmacist from using his professional judgment for the benefit of a patient's health and safety.

(d) Any pharmacy using an automated system must comply with all applicable state and federal laws and regulations. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 1985 MAR p. 1017, Eff. 7/26/85; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.818 SECURITY (1) The system shall contain adequate safeguards or security of the records to maintain the confidentiality and accuracy of the prescription or drug order information. Safeguards against unauthorized changes in data after the information has been entered and verified by the registered pharmacist shall be provided by the system. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 1985 MAR p. 1017, Eff. 7/26/85; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.819 SANITATION AND EQUIPMENT REQUIREMENTS

(1) Pharmacies shall at all times be operated by a registered pharmacist in a sanitary manner. There must be in use a safe and pure water supply and facilities for the proper storage and handling of supplies and stocks.

(2) Pharmacies shall have adequate space where prescriptions are filled or drugs compounded, containing suitable equipment in order to provide for an efficient pharmacy operation.

(3) Pharmacies shall contain and have ready for use all up-to-date items which are necessary in filling prescriptions, compounding drugs and the efficient operation of the pharmacy. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

Rules 24.174.820 and 24.174.821 reserved

NEXT PAGE IS 24-19691

24.174.822 CENTRAL FILLING BY HUB PHARMACIES (REPEALED) (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-321, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06; REP, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.823 CENTRALIZED PRESCRIPTION FILLING AND PROCESSING OF DRUG ORDERS (1) A pharmacy may outsource prescription drug order filling or processing to a central filling or processing pharmacy provided the pharmacies:

(a) have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and

(b) share a common electronic file.

(2) A pharmacy that outsources prescription drug order filling or processing to another pharmacy shall, prior to outsourcing a prescription drug order:

(a) notify the patient or the patient's agent that prescription filling or processing may be outsourced to another pharmacy;

(b) provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact; and

(c) clearly show the name, address, and telephone number of the delivering pharmacy on the prescription container.

(3) The patient shall have the choice not to have the prescription outsourced.

(4) Each pharmacy engaging in centralized prescription processing shall be jointly responsible for properly filling the prescription.

(5) The delivering pharmacy is responsible for providing patient counseling.

(6) All central filling or processing of prescription drug orders must be completed in a licensed pharmacy.

(7) Pharmacies providing central processing or central filling services to pharmacies in the state of Montana must be licensed in Montana.

(8) An out-of-state pharmacy providing central processing or central filling services to pharmacies in the state of Montana must be registered as an out-of-state mail service pharmacy and comply with all Montana statutes and rules regulating mail order pharmacies.

(9) A policy and procedure manual relating to centralized filling or processing activities shall be maintained at all pharmacies involved in centralized filling or processing. An electronic copy of the policy and procedure manual shall be submitted to the board. Thereafter the manual shall be available for inspection and copying by the board. The policies and procedures shall:

(a) outline the responsibilities of each of the pharmacies which must include but is not limited to:

(i) receiving, interpreting, or clarifying prescription orders;

(ii) entering data and transferring prescription information;

(iii) obtaining refill and substitution authorization information;

(iv) performing drug regimen review;

(v) interpreting clinical data for prior authorization dispensing;

(vi) performing therapeutic interventions; and

(vii) providing drug information.

(b) include a list of the name, address, telephone numbers, and license or registration number of the pharmacies participating in central filling or processing; and

(c) include policies and procedures for:

(i) protection of the confidentiality and integrity of patient information;

(ii) maintenance of appropriate records to identify the names, initials, or identification codes and specific activities of each of the pharmacists and/or technicians who performed any processing; and

(iii) compliance with federal, DEA, and state laws and regulations;

(iv) operation of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(v) annual review of the written policies and procedures and documentation of such review. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-321, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

NEXT PAGE IS 24-19719

Subchapter 9

Patient Counseling

24.174.901 PATIENT RECORDS (1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist or pharmacy technician under a board-approved utilization plan, shall make a reasonable effort to obtain, record, and maintain the following information:

(a) full name of the patient for whom the drug is intended;

(b) address and telephone number of the patient;

(c) patient's age or date of birth;

(d) patient's gender;

(e) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) The pharmacist or pharmacy technician under a board-approved utilization plan, shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease status of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

(3) A patient record shall be maintained for a period of not less than three years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form. (History: 37-7-201, MCA; IMP, 37-7-406, MCA; NEW, 1993 MAR p. 293, Eff. 2/26/93; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.902 PROSPECTIVE DRUG REVIEW (1) A pharmacist shall review the patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness by identifying:

(a) overutilization or underutilization;

(b) therapeutic duplication;

(c) drug-disease contraindications;

(d) drug-drug interactions;

(e) incorrect drug dosage or duration of drug treatment;

(f) drug-allergy interactions;

(g) clinical abuse/misuse.

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber. (History: 37-7-201, MCA; IMP, 37-7-406, MCA; NEW, 1993 MAR p. 293, Eff. 2/26/93; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.903 PATIENT COUNSELING (1) Upon receipt of a new prescription drug order or refill prescription drug order if deemed necessary by the pharmacist, and following a review of the patient's record, a pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling. Such elements may include the following:

(a) the name and description of the drug;

(b) the dosage form, dose, route of administration, and duration of drug therapy;

(c) intended use of the drug and expected action;

(d) special directions and precautions for preparation, administration, and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescription refill information;

(i) action to be taken in the event of a missed dose; and

(j) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) Each pharmacy shall have at least one area that offers appropriate visual and auditory patient confidentiality for patient counseling. This requirement shall go into effect three years from the date of enactment.

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples to include written information leaflets, pictogram labels, video programs, etc.

(4) Patient counseling, as described above and defined in this Act shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s). Any pharmacist dispensing medication to be self-administered outside an institution shall comply with all patient counseling statutes and rules.

(5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A record of the refusal shall be maintained by the pharmacist. (History: 37-7-201, MCA; IMP, 37-7-406, MCA; NEW, 1993 MAR p. 293, Eff. 2/26/93; AMD, 2000 MAR p. 2005, Eff. 7/28/00; TRANS, from Commerce, 2002 MAR p. 904.)

NEXT PAGE IS 24-19731

Subchapter 10

Out-of-State Mail Service Pharmacies

24.174.1001 REGISTRATION OF OUT-OF-STATE MAIL SERVICE PHARMACIES (1) No out-of-state pharmacy shall ship, mail or deliver prescription drugs and/or devices to a patient in this state unless registered by the Montana Board of Pharmacy. (History: 37-7-712, MCA; IMP, 37-7-703, MCA; NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.1002 CONDITIONS OF REGISTRATION (1) As conditions of registration, the out-of-state mail service pharmacy must comply with the following:

(a) be a legal entity registered and in good standing with the Montana Secretary of State;

(b) be registered and in good standing with the National Association of Boards of Pharmacy verified internet pharmacy practice sites (VIPPS) if registered after June 1, 2001;

(c) maintain, in readily retrievable form, records of legend drugs and/or devices dispensed to Montana patients;

(d) supply upon request, all information needed by the Montana Board of Pharmacy to carry out the board's responsibilities under the statutes and regulations pertaining to out-of-state mail service pharmacies;

(e) maintain pharmacy hours that permit the timely dispensing of drugs to Montana patients and provide reasonable access for the Montana patients to consult with a licensed pharmacist about such patients' medications;

(f) provide toll-free telephone communication consultation between a Montana patient and a pharmacist at the pharmacy who has access to the patient's records, and ensure that said telephone number(s) will be placed upon the label affixed to each legend drug container. A toll-free telephone number shall also be provided to the board to allow for compliance with all information requests by the board. (History: 37-7-712, MCA; IMP, 2-18-704, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA; NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; AMD, 2001 MAR p. 783, Eff. 5/11/01; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.1003 IDENTIFICATION OF PHARMACIST-IN-CHARGE OF DISPENSING TO MONTANA (1) Each out-of-state mail service pharmacy that ships, mails or delivers prescription drugs and/or devices to a patient in the state of Montana shall identify a pharmacist in charge of dispensing prescriptions for shipment to Montana. Each pharmacist so identified shall meet the following requirements:

(a) be licensed in good standing in the state in which the out-of-state mail service pharmacy is located;

(b) be properly listed on the application form prescribed by the board;

(c) comply with all applicable Montana laws and rules;

(d) notify the Montana board promptly of any relevant changes in employment or address, etc.;

(e) notify the Montana board promptly of any disciplinary actions initiated and/or finalized against the pharmacist's license. (History: 37-7-712, MCA; IMP, 37-7-703, MCA; NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.1004 CHANGE IN LOCATION (1) Whenever a mail service pharmacy changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The mail service pharmacy shall submit a new license application for the new location at least 30 days before such change occurs. (History: 37-7-201, 37-7-712, MCA; IMP, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.1005 CHANGE IN OWNERSHIP (1) When a mail service pharmacy changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner. The owner shall submit a new license application at least 30 days prior to the change in ownership.

(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

(3) The board must be notified in writing when five to 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity. (History: 37-7-201, 37-7-712, MCA; IMP, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

Rule 24.174.1006 reserved

NEXT PAGE IS 24-19745

24.174.1007 AGENT OF RECORD (1) Each out-of-state mail service pharmacy that ships, mails or delivers prescription drugs and/or devices to a patient in the state of Montana shall designate a resident agent in Montana for service of process.

(2) Any such out-of-state mail service pharmacy that does not so designate a resident agent and that ships, mails or delivers prescription drugs and/or devices in the state of Montana shall be deemed an appointment by such out-of-state mail service pharmacy of the Secretary of State to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such pharmacy growing out of or arising from such delivery.

(3) A copy of any such service of process shall be mailed to the out-of-state mail service pharmacy by the complaining party by certified mail, return receipt requested, postage prepaid, at the address of such out-of-state mail service pharmacy as designated on the pharmacy's application for registration in this state.

(4) If any such pharmacy is not registered in this state, service on the Secretary of State of Montana only shall be sufficient service. (History: 37-7-712, MCA; IMP, 37-7-703, MCA; NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.1008 USE OF PHARMACY TECHNICIANS BY OUT-OF-STATE MAIL SERVICE PHARMACIES (1) Any application for out-of-state mail service pharmacy registration from a facility located in a state which does not regulate the use of pharmacy technicians may not allow a pharmacist to supervise more than one supportive person at any one time in the compounding or dispensing of prescription drugs, unless approved by the board.

(2) Any application for out-of-state mail service pharmacy licensure from a facility located in a state which does regulate the use of pharmacy technicians shall provide information on the supervisor to technician ratio allowed in the resident state, and submit a utilization plan for the employment of pharmacy technicians. (History: 37-7-712, MCA; IMP, 37-7-703, MCA; NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.1009 COMPLIANCE (1) Each out-of-state mail service pharmacy shall comply with the following:

(a) all statutory and regulatory requirements of the state of Montana for controlled substances, including those that are different from federal law or regulation, unless compliance would violate the pharmacy drug laws or regulations of the state in which the pharmacy is located;

(b) all statutory and regulatory requirements of the state of Montana regarding drug product selection laws, unless compliance would violate the laws or regulations of the state in which the pharmacy is located;

(c) labeling of all prescriptions dispensed, to include but not be limited to identification of the product and quantity dispensed;

(d) all the statutory and regulatory requirements of the state of Montana for dispensing prescriptions in accordance with the quantities indicated by the prescriber, unless compliance would violate laws or regulations of the state in which the pharmacy is located. (History: 37-7-712, MCA; IMP, 37-7-701, 37-7-703, MCA; NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.1010 DISCIPLINARY ACTION (1) Except in emergencies that constitute an immediate threat to public health and require prompt action by the board, the Montana Board of Pharmacy shall file a complaint against any out-of-state mail service pharmacy that violates any statute or regulation of Montana with the board in which the out-of-state mail service pharmacy is located. If the board in the state in which the out-of-state mail service pharmacy is based fails to resolve the violation complained of within a reasonable time, disciplinary proceedings may be instituted in Montana before the board. (History: 37-7-712, MCA; IMP, 37-7-703, 37-7-704, 37-7-711, MCA; NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904.)

NEXT PAGE IS 24-19751

Subchapter 11

Institutional Pharmacies

24.174.1101 PERSONNEL (1) Each institutional pharmacy must be directed by a pharmacist-in-charge who is licensed to engage in the practice of pharmacy in the state of Montana and who is responsible for the storage, compounding, repackaging, dispensing and distribution of drugs within the facility. Depending upon the needs of the facility, pharmacy services may be provided on a full or part-time basis, with a mechanism for emergency service provided at all times. Contractual providers of pharmacy services shall meet the same requirements as pharmacies located within the institution.

(2) Registered pharmacy technicians or technicians-in-training may be utilized pursuant to the written policies and procedures of the institutional pharmacy. Exemptions to established ratios as defined in ARM 24.174.711 may be granted with board approval. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.)

Rules 24.174.1102 and 24.174.1103 reserved

24.174.1104 INSTITUTIONAL PHARMACIST AND PHARMACIST-IN-CHARGE RESPONSIBILITY (1) The pharmacy director/pharmacist-in-charge shall provide for applicable policies and procedures to ensure:

(a) mechanisms for receiving and verifying drug orders from prescribers and evaluating them for safety and therapeutic appropriateness based on patient parameters and dosing guidelines;

(b) appropriate filling and proper labeling of all containers from which drugs are to be dispensed or administered on an inpatient or outpatient basis;

(c) a system for the admixture of parenteral products accomplished within the pharmacy, and verification that the facility's department of nursing will provide education and training of nursing personnel regarding sterile technique, stability and compatibility of parenteral products not mixed within the pharmacy;

(d) appropriate clinical services and monitoring of outcomes, and the development of new areas of pharmaceutical care appropriate for that institution;

(e) a policy by which an offer is made to convey the discharge medication regimen to a patient's pharmacies;

(f) maintaining and distributing a list of emergency drugs, antidotes, and their doses throughout the institution;

(g) pharmacy participation in formulary development;

(h) participation in drug utilization review and monitoring of adverse drug reactions and development of procedures to avoid problems identified;

(i) evaluation of reported medication errors and development of procedures to prevent those errors;

(j) proper acquisition and secure, temperature-controlled storage of all prescription drugs;

(k) quality control of sterile and nonsterile pharmaceutical products, including procedures for identifying, removing and destroying outdated products;

(l) pharmacy safety and security;

(m) utilization of registered technicians or technicians in training;

(n) accurate distribution systems and secure, temperature-controlled storage of pharmaceutical products throughout the institution;

(o) unit-dosing of bulk pharmaceuticals, compounding and sterilization of drug products if applicable;

(p) the appropriate use, security and accountability of controlled substances;

(q) staff development and competency evaluation;

(r) maintenance of all required records; and

(s) compliance with all other requirements of the Montana Board of Pharmacy. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.)

Rules 24.174.1105 and 24.174.1106 reserved

24.174.1107 ABSENCE OF PHARMACIST IN INSTITUTIONAL SETTINGS

(1) During times that an institutional pharmacy does not have a pharmacist in attendance, arrangements must be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel by use of night cabinets, floor stock and, in emergency circumstances, by access to the pharmacy. A mechanism for providers and nursing to obtain pharmacy consultation must be available at all times in accordance with ARM 24.174.1101.

(2) If night cabinets are used to store drugs in the absence of a pharmacist, they must be locked and sufficiently secure to deny access to unauthorized persons, and must be located outside of the pharmacy area. Contents of night cabinets must be prepackaged. Only specifically authorized personnel may obtain access by key or combination, pursuant to a valid prescription order. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the facility, develop inventory listings of drugs included in these cabinets and determine who may have access.

(3) A complete verification audit of all inpatient orders and activity concerning the night cabinet or after-hours pharmacy entry must be conducted by a pharmacist, pharmacy technician, or other licensed designee of that pharmacist within 72 hours of the drugs having been removed from the night cabinet or pharmacy.

(4) Whenever any drug is not available from floor stock or night cabinets, and that drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy by an authorized registered nurse or licensed practical nurse in accordance with established policies and procedures. The responsible nurse shall be designated by the appropriate committee of the institutional facility.

(a) Removal of any drug from the pharmacy, floor stock, or night cabinet by an authorized nurse must be recorded on a suitable form showing the following information:

(i) patient name;

(ii) the patient's room number if applicable;

(iii) the name, strength, and quantity of drug removed;

(iv) the date and time the drug was removed;

(v) the signature of the nurse removing the drug; and

(vi) documentation of pharmacy review.

(b) in cases of medication not unit-dosed, the NDC number of the drug removed must also be recorded.

(5) The pharmacist-in-charge shall ensure that:

(a) written policies and procedures are established to implement the requirements of this rule;

(b) all drugs are properly labeled; and

(c) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements.

(6) A copy of the original drug order with the NDC number or other identifying code of the drug(s) provided may be faxed to the pharmacist. If the patient is an inpatient, a patient profile containing the patient's name, location, allergies, current medication regimen, and relevant laboratory values must be reviewed by a pharmacist within 72 hours. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

Rules 24.174.1108 through 24.174.1110 reserved

NEXT PAGE IS 24-19759

24.174.1111 DRUG DISTRIBUTION AND CONTROL IN AN INSTITUTIONAL FACILITY (1) The pharmacist-in-charge shall establish written policies and procedures for the safe and efficient distribution of drugs and provision of pharmaceutical care, including the mechanism by which drug review will be accomplished and documented. A current copy of such procedures must be on hand for inspection by the Board of Pharmacy.

(2) Automated dispensing devices must be stocked with drugs only by or under the supervision of a registered pharmacist. At the time of removal of any drug, the device must automatically make an electronic record indicating the date of removal, the name, strength, and quantity of drug removed, name of the patient for whom the drug was ordered, and the name or other identification of the person removing the drug. These records must be maintained for a period of two years.

(3) Drugs or herbal/alternative food supplement products brought into an institutional facility by a patient must not be administered unless they can be identified and their quality assured by a pharmacist, and their use has been authorized by the attending physician. If such drugs are not to be administered, the pharmacist-in-charge shall develop policies and procedures for storing them for return to the patient upon discharge or transferring them to an adult member of the patient's immediate family.

(4) Investigational drugs must be stored in and dispensed from the pharmacy only pursuant to written policies and procedures. Complete information regarding these drugs and their disposition must be maintained in the facility. The drug monograph and a signed patient consent form must be obtained and made available in accordance with state and federal guidelines.

(5) A sample drug policy must be established if samples are used.

(6) The safe handling, storage, and administration of medications within jails, correctional facilities, and detention facilities without onsite pharmacies shall be regulated as follows:

(a) Jails, correctional facilities, and detention facilities must have written policies and procedures in place, written by the responsible practitioner or authority, for the safe handling, storage, and administration of medications. Such policies shall address security of medications, procurement, proper storage and disposal of medications, training for those administering medication, methods for documenting that medications were given or refused, procedures for confirming that the inmate has ingested each medication, and the disposition of medications at discharge. Medications brought by or with an inmate upon admission to the jail, correctional facility, or detention facility must not be used unless specifically authorized by a physician at the jail, correctional facility, or detention facility or that physician's designee, and medication identity has been confirmed by a licensed health care professional. Prescription medications brought by an inmate from outside must be recorded on the inmate property record. If they are not used while the patient is incarcerated, they must be stored in a secure area until the inmate's release.

(b) Patient medications may be transferred from one jail, correctional facility, or detention facility to another if there is a secure method for ensuring that individual inmate prescriptions are not tampered with between locations and that containers are properly labeled. During transfer, medications requiring storage at room temperature should be subjected to external temperatures no greater than 86 degrees Fahrenheit. A method of transferring refrigerated medications from one jail, correctional facility, or detention facility to another must be addressed in policy and procedure. Medications transferred pursuant to the above regulations, in control of the transferring official at all time, may continue to be used for that patient.

(c) Emergency kits supplied and maintained by a registered pharmacist may be utilized if policies and procedures regulating their use are in place. Such emergency kits will comply with the requirements of ARM 24.174.1114.

(d) Jails, correctional facilities, and detention facilities without an on-site pharmacy that procures, stores, and administers prescription medications may request technical assistance from the board. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, 37-7-406, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

Rules 24.174.1112 and 24.174.1113 reserved

24.174.1114 USE OF EMERGENCY DRUG KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) In an institutional facility that does not have an in-house pharmacy, drugs may be provided for use by authorized personnel through emergency kits prepared by the registered pharmacist providing pharmaceutical services to the facility. Such emergency drug kits must meet all of the following requirements:

(a) a registered pharmacist shall prepare and seal the kit;

(b) the supplying pharmacist and the designated practitioner or appropriate committee of the institutional facility shall jointly determine the identity and quantity of drugs to be included in the kit;

(c) the kit must be locked and stored in a secure area to prevent unauthorized access and to ensure a proper storage environment for the drugs contained therein;

(d) all drugs in the kit must be properly labeled, including lot number and expiration date, and shall possess any additional information that may be required to prevent risk of harm to the patient;

(e) the exterior of the kit must be clearly labeled to indicate:

(i) its use and expiration date of its contents;

(ii) the name, address and telephone number of the supplying pharmacist; and

(iii) a statement indicating that the kit is to be used in emergency situations only pursuant to a valid drug order.

(2) Drugs shall be removed from emergency kits only by the supplying pharmacist or by authorized personnel pursuant to a valid drug order.

(3) The supplying pharmacist shall be notified of any entry into the kit. The supplying pharmacist shall have a mechanism defined in policy to restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.

(4) The expiration date of a kit must be the earliest date of expiration of any drug supplied in the kit. On or before the expiration date, the supplying pharmacist shall replace the expired drug.

(5) The supplying pharmacist shall, in conjunction with the appropriate institutional committee, be responsible for development of policies and procedures for safe and appropriate use and maintenance of emergency drug kits. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.)

Rules 24.174.1115 through 24.174.1120 reserved

24.174.1121 STERILE PRODUCTS (1) Policies and procedures must be prepared for the compounding, dispensing, delivery, administration, storage and use of sterile pharmaceutical products. The policies must include a quality assurance program for monitoring personnel qualifications and training in sterile technique, product storage, stability standards, and infection control. Policies and procedures must be current and available for inspection by a designee of the Board of Pharmacy.

(2) An institutional pharmacy compounding sterile products must have an isolated area designed to avoid unnecessary traffic and airflow disturbances.

(3) An institutional pharmacy compounding sterile products must utilize an appropriate aseptic environmental control device such as a laminar flow biological safety cabinet capable of maintaining Class 100 conditions during normal activity, or have policies and procedures in place limiting the pharmacy's scope of sterile product preparation.

(4) An institution preparing cytotoxic drugs must have a vertical flow Class II biological safety cabinet. Cytotoxic drugs must be prepared in a vertical flow Class II biological safety cabinet.

(a) Protective apparel including nonvinyl gloves, gowns and masks must be available, and gloves must be worn at all times.

(b) Appropriate containment techniques must be used in addition to aseptic techniques required for sterile product preparation.

(c) Prepared doses of cytotoxic drugs must be clearly identified, labeled with proper precautions and dispensed in a manner to minimize risk of cytotoxic spills.

(d) Disposal of cytotoxic waste must comply with all applicable local, state and federal laws.

(e) Written procedures for handling cytotoxic spills must be included in the policies and procedures manual.

(5) All parenteral admixtures must be labeled with date of preparation and expiration date clearly indicated, patient name and room number, name and strength and/or amount of drug and base solution, and any special handling or storage instructions.

(6) All aseptic environmental control devices must be certified by an independent contractor for operational efficiency at least every 12 months or when relocated, according to Federal Standard 209E. Prefilters must be inspected periodically and replaced if needed.

(7) Inspection and replacement dates must be documented and maintained for a period of at least two years.

(8) Documented records of ongoing quality assurance programs, justification of expiration dates chosen, and employee training records and technique audits must be available for inspection by the Board of Pharmacy. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.)

24.174.1122 OUTPATIENT CENTERS FOR SURGICAL SERVICES (1) The board shall annually register and inspect all outpatient centers for surgical services in Montana, regardless of pharmacy status.

(2) In an outpatient center for surgical services without an on-site pharmacy, drug distribution must be directed by a physician or consulting pharmacist licensed to practice in Montana and who is responsible for the security, storage, and distribution of drugs within the facility.

(3) The physician director or consulting pharmacist shall provide for applicable policies and procedures to ensure:

(a) proper acquisition and secure, temperature-controlled storage of all pharmaceuticals;

(b) security and accountability of controlled substances;

(c) quality control of sterile and nonsterile pharmaceutical products including procedures for identifying, removing, and destroying outdated products;

(d) evaluation of reported medication errors and development of procedures to prevent those errors;

(e) maintenance of all required records; and

(f) compliance with all requirements of the board.

(4) Ambulatory surgical centers that store and/or administer controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local, and DEA regulations. (History: 50-32-314, MCA; IMP, 50-32-314, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2008 MAR p. 1151, Eff. 6/13/08.)

Rules 24.174.1123 through 24.174.1140 reserved

NEXT PAGE IS 24-19775

24.174.1141 RETURN OF MEDICATION FROM LONG TERM CARE FACILITIES - DONATED DRUG PROGRAM (1) In facilities licensed by the Montana Department of Public Health and Human Services where United States pharmacopeia storage requirements are assured, unit-dosed legend drugs, with the exception of controlled substances, no longer needed by the patient for whom they were prescribed, may be transferred to a provisional permitted pharmacy for relabeling and dispensing free of charge to patients who are uninsured, indigent or have insufficient funds to obtain needed prescription drugs. Prescription medications may be dispensed pursuant to a valid prescription order. A usual and customary dispensing fee may be charged at the pharmacist's discretion.

(2) The pharmacist-in-charge of the provisional permitted pharmacy shall be responsible for determining the suitability of the legend drug for use. Medications must be unopened in sealed, unaltered unit dose containers that meet USP standards for light, moisture and air permeation. No product in which drug integrity cannot be assured shall be accepted for redispensing by the pharmacist.

(3) A redispensed prescription medication must be assigned the expiration date stated on the unit dose packaging. Medications packaged in unit dose form within a pharmacy must be given an expiration date of one year or actual date of expiration of the medication, whichever comes first, and must not be repackaged.

(4) No medication can be redistributed more than once.

(5) Only authorized personnel shall carry out the physical transfer of medication in either facility, pursuant to established policies and procedures.

(6) The patient's name and other identifying marks must be obliterated from packaging prior to transfer. The drug name, strength, lot number and expiration date must remain clearly visible on the packaging.

(7) An inventory list of drugs transferred, including expiration dates, must accompany the drugs, and must be maintained in the provisional permitted pharmacy for a period of two years.

(8) Policies and procedures to document safe storage and transfer of unneeded medications must be written and adhered to by the facilities involved, and must be available for inspection by an authorized representative of the Montana Board of Pharmacy or Department of Public Health and Human Services. (History: 37-7-201, 37-7-1401, MCA; IMP, 37-7-201, 37-7-1401, 37-7-1402, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.)

Subchapter 12

Wholesale Drug Distributors Licensing

24.174.1201 WHOLESALE DRUG DISTRIBUTOR LICENSING (1) Every person engaged in manufacturing, wholesale distribution, or selling of drugs, medicines, chemicals, poisons for medicinal purposes, medical gases, or legend devices other than to the consuming public or patient, in the state of Montana, shall be licensed annually by the board. Each applicant shall:

(a) be a legal entity registered and in good standing with the Montana Secretary of State;

(b) file an application on a form prescribed by the board;

(c) pay the appropriate licensing and registration fees; and

(d) meet the requirements of 37-7-604, MCA.

(2) The wholesale drug distributor license shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

(3) No license may be issued to any wholesale distributor whose intended place of business is a personal residence.

(4) A separate license is required for each separate location where drugs are stored. If a wholesaler distributes prescription drugs from more than one facility, the wholesaler must obtain a license for each facility.

(5) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations. Wholesale drug distributors who deal in controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local, and DEA regulations.

(6) Manufacturers, distributors, and suppliers of medical gases shall operate in compliance with applicable federal, state, and local laws and regulations. Manufacturers, distributors, and suppliers of medical gases shall register with the board to obtain the appropriate endorsement on their wholesale drug distributor license. (History: 37-7-201, 37-7-610, MCA; IMP, 37-7-603, 37-7-604, 37-7-605, 37-7-606, MCA; NEW, 1992 MAR p. 2135, Eff. 8/14/92; AMD, 1999 MAR p. 2438, Eff. 10/22/99; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.1202 MINIMUM INFORMATION REQUIRED FOR LICENSURE

(1) The following information shall be supplied by each applicant for wholesale drug distributor licensure or renewal:

(a) the name, full business address, and telephone number of the licensee;

(b) all trade or business names used by the licensee;

(c) the name, address, telephone number, and title of the designated person in charge of the facility;

(d) whether the ownership or operation is a partnership, corporation, or sole proprietorship;

(e) proof of registration with the Montana Secretary of State;

(f) if out-of-state, proof of corresponding licensure in good standing in the state in which the applicant resides;

(g) the federal tax identification number of the company; and

(h) written documentation in compliance with the information required under 37-7-604, MCA.

(2) Any changes in information contained in (1) shall be submitted to the board within 30 days of the change. Any changes in location or ownership require that a new license application be filed with the board at least 30 days prior to the change. (History: 37-7-201, 37-7-610, MCA; IMP, 37-7-604, 37-7-605, MCA; NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.1203 PERSONNEL (1) Each wholesale drug distributor shall require each person employed in any prescription drug wholesale activity to have sufficient education, training and experience in any combination, sufficient for that person to:

(a) complete assigned work in a manner which maintains the quality, safety and security of the drug products in accordance with Title 37, MCA;

(b) assume responsibility for compliance with the licensing requirements of Title 37, MCA. (History: 37-7-201, 37-7-610, MCA; IMP, 37-7-604, MCA; NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.1204 MEDICAL GAS DISTRIBUTOR (1) Every person engaged in the manufacture or distribution of medical gases other than to the consuming public or a patient, in the state of Montana, shall register annually with the board. Each applicant shall:

(a) provide proof of registration with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with all FDA requirements;

(b) register with the board as a wholesale drug distributor;

(c) file an application to register as a medical gas distributor on a form prescribed by the board; and

(d) pay the appropriate registration fee.

(2) The wholesale drug distributor license with the medical gas distributor endorsement shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

(3) A medical gas distributor shall establish and implement written procedures for maintaining records pertaining to medical gas production, processing, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law.

(a) Records shall be retained for at least two years after distribution or one year after the expiration date of the medical gas, whichever is longer.

(b) Records shall be readily available for review by the board, its inspector, or the FDA. (History: 37-1-134, 37-7-201, 37-7-610, MCA; IMP, 37-7-604, 37-7-605, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.1205 MEDICAL GAS SUPPLIER (1) Every person engaged in supplying medical gases to the consuming public, or to a patient or a patient's agent, in the state of Montana that is not a licensed pharmacy shall register annually with the board. Each applicant shall:

(a) register with the board as a wholesale drug distributor;

(b) file an application to register as a medical gas supplier on a form prescribed by the board; and

(c) pay the appropriate registration fee.

(2) The wholesale drug distributor license with the medical gas supplier endorsement shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

(3) A medical gas supplier shall not:

(a) supply prescription medications, except medical gases, without appropriate licensure as a pharmacy;

(b) manufacture or distribute medical gases without appropriate licensure as a medical gas distributor; or

(c) instruct patients regarding clinical use of equipment, or provide any monitoring, assessment, or other evaluation of therapeutic effects without appropriate licensure as a respiratory care practitioner.

(4) A medical gas supplier shall supply medical gas only pursuant to prescription order by an authorized prescriber.

(5) A medical gas supplier must label each medical gas container with the name, address, and telephone number of the supplier.

(6) A medical gas supplier shall establish and implement written procedures for maintaining records pertaining to the acquisition and supply of, and complaints related to, medical gases.

(7) Records shall be retained for at least three years after supply to a patient or one year after the expiration date of the medical gas, whichever is longer.

(8) Records shall be readily available for review by the board or its inspector. (History: 37-1-134, 37-7-201, 37-7-610, MCA; IMP, 37-7-604, 37-7-605, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.1206 MEDICAL GAS FEE SCHEDULE (1) The fees for registration to manufacture, distribute, or supply medical gases shall be assessed according to the following schedule:

REGISTRATION	ANNUAL FEE
(a) medical gas distributor	$75
(b) medical gas supplier	75

(History: 37-1-134, 37-7-201, 37-7-610, MCA; IMP, 37-7-604, 37-7-605, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.1207 CHANGE IN LOCATION (1) Whenever a wholesale drug distributor facility changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The wholesale drug distributor facility shall submit a new license application for the new location at least 30 days before such change occurs. (History: 37-7-201, 37-7-610, MCA; IMP, 37-7-604, 37-7-605, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

24.174.1208 CHANGE IN OWNERSHIP (1) When a wholesale drug distributor changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner. The owner shall submit a new license application at least 30 days prior to the change in ownership.

(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

(3) The board must be notified in writing when five to 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity. (History: 37-7-201, 37-7-610, MCA; IMP, 37-7-604, 37-7-605, MCA; NEW, 2007 MAR p. 1936, Eff. 11/22/07.)

Rules 24.174.1209 and 24.174.1210 reserved

24.174.1211 MINIMUM REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS (1) All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(a) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) have a physically separate area for storage of all prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d) be maintained in a clean and orderly condition; and

(e) be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) All facilities used for wholesale drug distribution shall be secure from unauthorized entry as provided for in 37-7-604, MCA, and as follows:

(a) access from outside the premises shall be kept to a minimum and be well-controlled;

(b) the outside perimeter of the premises shall be well-lighted; and

(c) entry into areas where prescription drugs are held shall be limited to authorized personnel.

(3) All facilities shall be equipped with a security system to detect entry after hours.

(4) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(5) All drugs shall be stored at temperatures and under conditions in accordance with the requirements, if any, in the labeling of such drugs, or with requirements in the current edition of the United States Pharmacopeia/National Formulary, published by the United States Pharmacopeia Convention Inc., which is available for inspection at the pharmacy library at the University of Montana School of Pharmacy and Allied Health Sciences, Missoula, MT 59812-1075.

(a) If no storage requirements are established for a drug, the drug may be held at "controlled room temperature," as defined in the United States Pharmacopeia/National Formulary, to help ensure that its identity, strength, quality and purity are not adversely affected.

(b) Manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document proper storage of prescription drugs.

(c) The record keeping requirements in these rules shall be followed for all stored drugs.

(6) A stock of prescription drugs, adequate to service the ordinary needs of practitioners and pharmacies with which the wholesaler transacts business, must be maintained.

(7) A wholesaler may not maintain a stock of controlled substances unless the wholesaler ordinarily sells controlled substances to practitioners and pharmacies with which the wholesaler transacts business. (History: 37-7-201, 37-7-610, MCA; IMP, 37-7-604, MCA; NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.1212 MINIMUM REQUIREMENTS FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS (1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution of or other disposition of drugs. These records shall include the following information:

(a) the source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(b) the identity and quantity of the drugs received and distributed or disposed of;

(c) the dates of receipt and distribution or other disposition of the drugs;

(d) evidence of the existence of a written franchise, license, or other agreement between a manufacturer and wholesaler to distribute prescription drugs;

(e) evidence of completion of two or more purchases of prescription drugs in any six month period; and

(f) a complete list of all wholesale distributors and manufacturers from whom the wholesaler purchased prescription drugs within the last year.

(2) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.

(3) Records described in this part that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at central locations apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(4) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of drugs. They must include policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(5) Wholesale drug distributors shall include the following written policies and procedures:

(a) a procedure where the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate;

(b) a procedure to be followed for handling recalls and withdrawals of drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(i) an action initiated at the request of the Food and Drug Administration, or other federal, state or local law enforcement or other government agency, including the Board of Pharmacy;

(ii) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(c) a procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(d) a procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of the drugs. This documentation shall be maintained for two years after disposition of the outdated drugs. (History: 37-7-201, 37-7-610, MCA; IMP, 37-7-604, 37-7-609, MCA; NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.1213 NATIONAL CLEARINGHOUSE FOR WHOLESALE DRUG DISTRIBUTOR LICENSING (1) Any wholesale drug distributor may apply for a license in Montana through a national clearinghouse for licensing of wholesale drug distributors, which has been approved by the board, by meeting the minimum requirements for licensure in Title 37, MCA, and complying with all requirements of the approved national clearinghouse. (History: 37-7-201, 37-7-610, MCA; IMP, 37-7-604, 37-7-605, 37-7-606, 37-7-607, MCA; NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904.)

Subchapter 13

Telepharmacy

Rule 24.174.1301 reserved

24.174.1302 TELEPHARMACY OPERATIONS (1) A remote telepharmacy site shall be connected to its parent pharmacy via computer, video, and audio link.

(2) A site cannot be licensed as a remote telepharmacy site if it is located within a ten mile radius of an existing pharmacy.

(3) A remote telepharmacy site manned by a registered pharmacy technician shall access and use the parent pharmacy's central processing unit.

(4) A remote telepharmacy site shall comply will all the requirements of pharmacy rules and statutes of Montana. The remote telepharmacy site is considered to be under the personal charge of the pharmacist at the parent pharmacy.

(a) The remote telepharmacy site must have a registered pharmacy technician present and a working computer, video, and audio link to a pharmacist at the parent pharmacy to have the prescription area open.

(b) The technician at the remote telepharmacy site must:

(i) be currently registered with the board;

(ii) be currently certified with the Pharmacy Technician Certification Board; and

(iii) have at least six months of active experience as a pharmacy technician.

(c) The technician may unlock the prescription and storage areas. While the technician is on duty, the prescription area may remain open. Security standards for pharmacies shall be maintained at all times pursuant to ARM 24.174.814.

(d) The technician will be subject to all rules of ARM 24.174.701 through 24.174.714.

(e) All prescription records and consecutive prescription numbers must be maintained at the parent pharmacy. The remote telepharmacy site must transmit copies of new prescriptions via secure electronic means to the parent pharmacy, keeping the original prescription blank at the remote telepharmacy site.

(f) Prescriptions filled at the remote telepharmacy site must be distinguishable in some manner from those filled at the parent pharmacy.

(g) Daily reports for both the parent pharmacy and remote telepharmacy site must be maintained at the parent pharmacy.

(h) The remote telepharmacy site may have a prescription inventory. Prescription medications including controlled substances shall be securely maintained at the remote telepharmacy site in accordance with current Montana pharmacy statutes and rules.

(i) If controlled substances are dispensed or handled, both the remote telepharmacy site and the parent pharmacy must be registered with the DEA and must obtain individual DEA numbers.

(j) All records must be stored at the parent pharmacy, except those required by DEA to be at a DEA registered site.

(k) The software system utilized must be able to generate labels from the parent pharmacy or at the remote telepharmacy site.

(l) The input of drug information may be done by a pharmacist at the parent pharmacy or a technician at either location if verified by a pharmacist.

(m) New prescriptions may be received at the parent pharmacy and entered there with a label printing at the remote telepharmacy site.

(n) New prescriptions received at the remote telepharmacy site may be entered into the computer system at the remote telepharmacy site. The pharmacist at the parent pharmacy remains responsible for all verification, interaction checking, and profile review.

(o) All filled prescriptions must have a label meeting the requirements of ARM 24.174.511 attached to the final drug container before the pharmacist verifies the dispensing process.

(p) Unless the remote telepharmacy site is a remote telepharmacy dispensing machine site, a pharmacist shall compare via video link the stock bottle, drug dispensed, and strength. The entire label must be checked for accuracy on the video link.

(q) The computer, video, and audio link must be operational and the remote telepharmacy site must be closed if the link malfunctions, unless a pharmacist is working at the remote site.

(r) A code containing both the pharmacist's and technician's initials must appear on the fill screen, patient profile, and prescription label.

(s) No prescription medication may be released to a patient until approved by a pharmacist in person or via the computer, video, and audio link.

(t) The pharmacist shall counsel the patient or the patient's agent via video and audio link on all new prescriptions, but may provide counseling on refills only when the pharmacist deems additional counseling necessary.

(u) When the technician is not present, dispensing and counseling via video and audio link may be done using a secure alternate delivery system with prior approval of the board.

(v) The license holder or the pharmacist-in-charge of the parent pharmacy shall apply for a license for the remote telepharmacy site.

(w) As dispensing is considered to be done by the pharmacist, the pharmacist shall be responsible for and held accountable for dispensing at the remote telepharmacy site.

(x) Policies and procedures must be in place to ensure the safe and effective distribution of pharmaceutical products and delivery of required pharmaceutical care.

(y) The pharmacist at the parent pharmacy shall perform an ongoing analysis of incident reports and outcomes, with appropriate corrective action taken when necessary to ensure patient safety.

(z) The pharmacist at the parent pharmacy or that person's designee shall conduct and complete monthly inspections of the remote telepharmacy site. Inspection criteria must be included in the policies and procedures for the site. The inspection report must be available for review at the next board inspection. (History: 37-7-201, MCA; IMP, 37-7-101, 37-7-201, 37-7-321, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.1303 REMOTE TELEPHARMACY DISPENSING MACHINE SITES

(1) Remote telepharmacy dispensing machine sites contain prescription inventory which is secured in an automated dispensing device connected to the central processing unit at the parent pharmacy.

(2) A site cannot be licensed as a remote telepharmacy dispensing machine site if it is located within a ten mile radius of an existing pharmacy.

(3) A pharmacist must approve all outpatient prescriptions before they are dispensed, unless the prescription is directly dispensed by a person authorized to prescribe.

(4) All filled prescriptions must have a label that meets the requirements of ARM 24.174.511 attached to the final drug container.

(5) A licensed pharmacist at the parent site shall perform counseling and professional consultation via audio and video link as required by ARM 24.174.903, unless the prescription is directly dispensed by a person authorized to prescribe.

(6) Registered technicians involved in stocking and removal of prescription medications under this rule must have at least 80 hours of pretraining in bar coding technology. All requirements of ARM 24.174.701 through 24.174.714 will apply, excluding the technician certification requirement of ARM 24.174.702.

(7) Policies and procedures of the parent pharmacy and the remote telepharmacy dispensing machine site must address all aspects of the telepharmacy operation, including stocking procedures and removal of outdated prescription medications.

(8) The pharmacist at the parent pharmacy shall perform an ongoing analysis of incident reports and outcomes, with appropriate corrective action taken when necessary to ensure patient safety.

(9) The pharmacist-in-charge of the parent pharmacy or that person's designee shall conduct and complete monthly inspections of the remote telepharmacy dispensing machine site. Inspection criteria must be included in the policies and procedures for the site. The inspection reports must be available for review at the next board inspection.

(10) Remote telepharmacy dispensing machine sites must be licensed with the board by November 30 of each year, and will be subject to random inspection by board inspectors.

(11) This rule does not apply to institutional satellite pharmacies as defined in ARM 24.174.301. (History: 37-7-201, MCA; IMP, 37-7-101, 37-7-201, 37-7-321, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06.)

Subchapter 14

Dangerous Drug Act

24.174.1401 REQUIREMENTS FOR REGISTRATION (1) The board shall register a person to manufacture dangerous drugs (as defined in 50-32-101, MCA) included in Schedules I through V upon the following conditions:

(a) applicant is registered for such purposes pursuant to the Federal Controlled Substances Act of 1970;

(b) the applicant has made proper application and has paid the applicable fee; and

(c) the category of manufacturer as above-stated shall include only those applicants who are engaged in the manufacturing of dangerous drugs within the state of Montana.

(2) The board shall register a person or entity to distribute dangerous drugs included in Schedules I through V under the following conditions:

(a) applicant is registered for such purpose pursuant to the Federal Controlled Substances Act of 1970;

(b) the applicant has made proper application and paid the applicable fee;

(c) the category of distributor as above-stated shall include any person or entity who distributes dangerous drugs or samples thereof within the state of Montana and may include a manufacturer not otherwise required to be registered if such manufacturer also distributes dangerous drugs or samples thereof within the state of Montana; and

(d) representatives of drug manufacturers who distribute controlled substance samples to licensed practitioners shall be exempt from the requirement of registration.

(3) The board shall register a person to analyze or conduct research with narcotic dangerous drugs in Schedules II through V upon making proper application and paying the applicable fee.

(4) The board shall register a person to analyze or conduct research with dangerous drugs in Schedule I, if:

(a) the applicant is a practitioner licensed under the laws of this state;

(b) the applicant has furnished the board evidence of registration for such purpose pursuant to the Federal Controlled Substances Act of 1970;

(c) the applicant has furnished the board a complete resume of all research proposed relative to any dangerous drugs. Such resume must be a duplicate of an application submitted to the DEA; and

(d) the applicant has made proper application and paid the applicable fee. (History: 50-32-103, MCA; IMP, 50-32-306, 50-32-308, MCA; NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.1402 RENEWALS (1) All applications for registration shall be made on forms provided by the board and shall be filed with the board.

(2) Renewal notices will be sent as specified in ARM 24.101.414.

(3) The provisions of ARM 24.101.408 apply.

(4) The registrant shall prominently display the certificate of registration to be visible to the public. (History: 50-32-103, MCA; IMP, 37-1-141, 50-32-301, MCA; NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 1999 MAR p. 2438, Eff. 10/22/99; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1583, Eff. 7/1/06.)

24.174.1403 APPLICATION FORMS (1) If any person is required to be registered and is not so registered and is applying for registration to manufacture or distribute dangerous drugs in Schedules I through V, the person shall apply on a form prescribed by the board.

(2) If any person is required to be registered and is not so registered and is applying for registration to dispense dangerous drugs in Schedules II through V, the person shall apply on a form prescribed by the board.

(3) If any person is required to be registered and is not so registered and is applying for registration to analyze or conduct research with dangerous drugs in Schedules I through V, the person shall apply on a form prescribed by the board.

(4) Any licensee applying for renewal of registration to manufacture or distribute dangerous drugs in Schedules I through V, the licensee shall apply on a form prescribed by the board.

(5) Any licensee applying for renewal to dispense dangerous drugs in Schedules II through V, the licensee shall apply on a form prescribed by the board. (History: 50-32-103, MCA; IMP, 50-32-306, 50-32-308, MCA; NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.1404 REQUIRED RECORDS (1) As used in this subchapter, the term "records" means:

(a) those records and inventories maintained by persons registered to manufacture, distribute, analyze or dispense dangerous drugs or samples thereof in conformance with record keeping and inventory requirements of federal statute and regulation, (21 CFR 304), and as they may be amended from time-to-time.

(2) Manufacturers and distributors shall be required to keep such records as are required by federal statutes and regulations, (21 CFR 304), and as they may be amended from time-to-time.

(3) Separate records required:

(a) registrants' inventories and records of dangerous drugs listed in Schedules I and II shall be maintained separately from all records of the registrant; and

(b) registrants' inventories and records of dangerous drugs listed in Schedules III through V shall be maintained according to federal statutes and regulations as they may be amended from time-to-time. (History: 50-32-103, MCA; IMP, 50-32-309, MCA; NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904.)

Rules 24.174.1405 through 24.174.1410 reserved

24.174.1411 SECURITY REQUIREMENTS (1) All applicants and registrants shall establish and maintain effective written controls and procedures to guard against theft and diversion of dangerous drugs into other than legitimate medical, scientific or industrial channels.

(2) The registrant shall not employ as an agent or employee any person who has access to dangerous drugs, who has had a federal or state application for registration denied or his registration revoked at any time, or has been convicted of a felony offense under any state or federal law relating to dangerous drugs or convicted of any other felony.

(3) The registrant shall notify the Board of Pharmacy in writing by forwarding a copy of the applicable DEA form reporting the theft or loss of any dangerous drugs upon discovery of such theft or loss. The notification shall contain a list of all dangerous drugs stolen or lost.

(4) The registrant shall notify law enforcement officials of any theft or loss of any dangerous drug promptly upon discovery of such theft or loss. (History: 50-32-103, MCA; IMP, 50-32-106, MCA; NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02.)

24.174.1412 ADDITIONS, DELETIONS, AND RESCHEDULING OF DANGEROUS DRUGS (1) The Board of Pharmacy hereby adopts the schedule of dangerous drugs as defined in 21 CFR 1308, et. seq. April 1, 1999. Copies are available from the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, MT 59620-0513. (History: 50-32-103, 50-32-203, MCA; IMP, 50-32-103, 50-32-202, 50-32-203, 50-32-209, 50-32-222, 50-32-223, 50-32-224, 50-32-225, 50-32-226, 50-32-228, 50-32-229, 50-32-231, 50-32-232, MCA; NEW, Eff. 9/16/71; EMERG, AMD, Eff. 5/5/74; AMD, Eff. 9/4/75; AMD, Eff. 2/5/76; AMD, Eff. 3/7/76; AMD, Eff. 4/5/76; AMD, Eff. 9/5/76; AMD, 1978 MAR p. 393, Eff. 3/25/78; AMD, 1978 MAR p. 1740, Eff. 12/29/78; AMD, 1979 MAR p. 199, Eff. 3/1/79; AMD, 1980 MAR p. 1720, Eff. 6/27/80; AMD, 1981 MAR p. 625, Eff. 6/26/81; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1984 MAR p. 589, Eff. 4/13/84; AMD, 1984 MAR p. 1567, Eff. 10/26/84; AMD, 1985 MAR p. 1017, Eff. 7/16/85; AMD, 1986 MAR p. 1957, Eff. 11/29/86; AMD, 1988 MAR p. 271, Eff. 2/12/88; AMD, 1989 MAR p. 1193, Eff. 8/18/89; AMD, 1995 MAR p. 2689, Eff. 12/8/95; AMD, 1999 MAR p. 344, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

Subchapters 15 through 20 reserved

Subchapter 21

Renewals and Continuing Education

24.174.2101 PHARMACIES - ANNUAL RENEWAL (1) All pharmacies must renew their license annually with the board, in accordance with ARM 24.101.413. No pharmacy is allowed to operate without a currently renewed license. (History: 37-7-201, MCA; IMP, 37-7-321, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1999 MAR p. 2438, Eff. 10/22/99; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.2102 PHARMACY TECHNICIAN - RENEWAL (1) Pharmacy technicians will be required to renew each year on the date set forth in ARM 24.101.413.

(2) To assure the continuing competence of a pharmacy technician, proof of continued certification will be required at the time of renewal. (History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 86, Eff. 1/18/02.)

24.174.2103 RENEWALS (1) Renewal notices will be sent as specified in ARM 24.101.414 prior to the renewal date set by ARM 24.101.413.

(a) The notice will state the annual pharmacist's license renewal fee.

(b) The notice will state the continuing education requirements and any other information considered pertinent for the licensee's understanding of the renewal requirements.

(c) Notice will be considered as properly mailed when addressed to the current address on file with the board.

(2) The annual renewal notice shall be returned to the board with the appropriate fee and a representation of having satisfactorily completed continuing education requirements signed by the licensee. Incomplete renewal applications will not be processed and will be returned to the applicant.

(3) The annual renewal notice shall be returned to the board with the appropriate fee and a representation of having satisfactorily completed continuing education requirements signed by the licensee. Incomplete renewal applications will not be processed and will be returned to the applicant.

(a) The board shall randomly select submitted renewal notice forms for audit and verification of the approved continuing education programs listed. It will be the responsibility of each pharmacist to maintain his or her own records of attendance or completion and make them available upon request.

(4) The provisions of ARM 24.101.408 apply. (History: 37-1-319, MCA; IMP, 37-1-141, 37-1-306, MCA; NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 1999 MAR p. 2438, Eff. 10/22/99; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1583, Eff. 7/1/06.)

24.174.2104 REGISTERED PHARMACIST CONTINUING EDUCATION - REQUIREMENTS (1) The nationally accepted measurement of continuing education, the continuing education unit (CEU), will be the measurement employed by the board. Ten hours of approved continuing education credit equal one CEU.

(2) The board will require 1.5 CEU for each fiscal year.

(a) This requirement will not pertain to a pharmacist applying for his or her first license renewal.

(b) Only an additional 1.5 CEU may be accumulated and applied to the following year.

(c) A minimum of 0.5 CEU is to be obtained in approved group program.

(3) In order to receive Montana license renewal, any Montana-licensed pharmacist residing in another state shall meet Montana's requirements for continuing education. (History: 37-1-319, MCA; IMP, 37-1-306, MCA; NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.2105 REGISTERED PHARMACIST CONTINUING EDUCATION - SUBJECTS (1) Continuing pharmaceutical education will include, but will not be limited to, appropriate professional post graduate education in any of the following subjects:

(a) properties and actions of drugs and dosage forms;

(b) etiology, pathophysiology, clinical course, therapy and prognosis of diseases;

(c) pharmacy practice; and

(d) legal, psychological and socioeconomic aspects of health care delivery. (History: 37-1-319, MCA; IMP, 37-1-306, MCA; NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.2106 REGISTERED PHARMACIST CONTINUING EDUCATION - APPROVED PROGRAMS (1) Continuing education programs sponsored by providers that are approved by the following organizations will automatically qualify for continuing education credit:

(a) the American Council on Pharmaceutical Education (ACPE);

(b) programs that have been approved for Continuing Medical Education (CME) by a state Board of Medical Examiners or its equivalent; or

(c) the American Board of Medical Specialties.

(2) Pharmacists may receive CEU for programs other than those on the ACPE list of providers by applying for prior approval by the board or its designee. The forms and guidelines for applying for approval are available from the board office.

(3) Pharmacists participating in programs that have not received prior approval risk disallowance of credit. (History: 37-1-319, MCA; IMP, 37-1-306, MCA; NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1986 MAR p. 945, Eff. 5/30/86; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2003 MAR p. 109, Eff. 12/27/02.)

24.174.2107 REGISTERED PHARMACIST CONTINUING EDUCATION - NONCOMPLIANCE (1) Failure to meet the license renewal requirements set forth in ARM 24.101.413 will be cause for the license to lapse. For reinstatement, the applicant shall have completed the continuing education requirements and certify that fact to the board as stated in ARM 24.174.2103. (History: 37-1-319, MCA; IMP, 37-1-141, 37-1-306, MCA; NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 1999 MAR p. 2438, Eff. 10/22/99; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1583, Eff. 7/1/06.)

Subchapter 22 reserved

NEXT PAGE IS 24-19915

Subchapter 23

Unprofessional Conduct

24.174.2301 UNPROFESSIONAL CONDUCT (1) The board defines "unprofessional conduct" as follows:

(a) engaging in any activity which violates state and federal statutes and rules governing the practice of pharmacy;

(b) dispensing an outdated or questionable product;

(c) dispensing a cheaper product and charging for a more expensive product;

(d) charging for more dosage units than are actually dispensed;

(e) altering prescriptions or other records which the law requires pharmacies and pharmacists to maintain;

(f) dispensing medication without proper authorization;

(g) defrauding any persons or government agency receiving pharmacy services;

(h) placing a signature on any affidavit pertaining to any phase of the practice of pharmacy which the pharmacist knows to contain false information;

(i) any act performed in the practice of pharmacy which is hostile to the public health and which is knowingly committed by the holder of a license;

(j) buying, selling, purchasing or trading any prescription drug samples or offering to sell, purchase or trade drug samples. A "drug sample," as used herein, is defined to mean a unit of a prescription drug which is not intended to be sold and is intended to promote the sale of a drug;

(k) conviction, including conviction following a plea of nolo contendere, of an offense involving moral turpitude, whether misdemeanor or felony, and whether or not an appeal is pending;

(l) fraud, misrepresentation, deception or concealment of a material fact in applying for or securing a license, or license renewal, or in taking an examination required for licensure; as used herein, "material" means any false or misleading statement or information;

(m) use of a false, fraudulent or deceptive statement in any document connected with the practice of pharmacy;

(n) having been subject to disciplinary action of another state or jurisdiction against a license or other authorization to practice pharmacy, based upon acts or conduct by the licensee similar to acts or conduct that would constitute grounds for disciplinary actions under Title 37, chapter 7, MCA or these rules; a certified copy of the record of the action taken by the other state or jurisdiction is evidence of unprofessional conduct.

(o) willful disobedience of a rule adopted by the board, or an order of the board regarding evaluation or enforcement of discipline of a licensee;

(p) habitual intemperance or excessive use of an addictive drug, alcohol or any other substance to the extent that the use impairs the user physically or mentally;

(q) failing to furnish to the board or its investigators or representatives information legally requested by the board.

(r) failing to cooperate with a lawful investigation conducted by the board;

(s) conviction or violation of a federal or state law regulating the possession, distribution or use of a controlled substance, as defined by the federal Food and Drug Administration or successors, whether or not an appeal is pending;

(t) failure to transfer pertinent and necessary patient records to another licensed pharmacy, the patient or the patient's representative when requested to do so by the patient or the patient's legally designated representative;

(u) failure to comply with an agreement the licensee has entered into with the impaired pharmacist program. (History: 37-1-319, 37-7-201, MCA; IMP, 37-1-316, MCA; NEW, 1981 MAR p. 625, Eff. 6/26/81; AMD, 1989 MAR p. 1193, Eff. 8/18/89; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2001 MAR p. 783, Eff. 5/11/01; TRANS, from Commerce, 2002 MAR p. 904.)

NEXT PAGE IS 24-19927

Subchapter 24

Disciplinary/Complaint Procedures

24.174.2401 SCREENING PANEL (1) The board screening panel shall consist of three board members, including the two pharmacist members who have served longest on the board, and one other member as appointed by the board president. The board president may reappoint screening panel members as necessary at the president's discretion. (History: 37-7-201, MCA; IMP, 37-1-307, MCA; NEW, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.)

24.174.2402 COMPLAINT PROCEDURE (1) A person, government or private entity may submit a written complaint to the board charging a licensee or license applicant with a violation of board statutes or rules, and specifying grounds for the complaint.

(2) Complaints must be in writing, and shall be filed on the proper complaint form prescribed by the board.

(3) Upon receipt of the written complaint form, the board office shall log in the complaint and assign it a complaint number. The complaint shall then be sent to the licensee or license applicant complained about for a written response. Upon receipt of the licensee's or license applicant's written response, both complaint and response shall be considered by the screening panel of the board for appropriate action including dismissal, investigation or a finding of reasonable cause of violation of a statute or rule. The board office shall notify both complainant and licensee or license applicant of the determination made by the screening panel.

(4) If a reasonable cause violation determination is made by the screening panel, the Montana Administrative Procedure Act shall be followed for all disciplinary proceedings. (History: 37-7-201, MCA; IMP, 37-1-308, 37-1-309, MCA; NEW, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904.)

24.174.2403 LEGAL SUSPENSION OR REVOCATION (1) All licensed pharmacists and operators of pharmacies in the state of Montana must adhere to all the laws of the state of Montana and the rules of the board pertaining to pharmacists and operators of pharmacies and any violation thereof may constitute a cause for the revocation of such licenses.

(2) If an intern pharmacist is found or allowed to work in a pharmacy without the supervision of a registered pharmacist, meaning that the intern is allowed to work a shift by himself/herself, it may be cause for the board to cancel his or her internship in said pharmacy and may be cause for suspension or revocation of his or her intern pharmacist license. The board may in its discretion ask for surrender, suspension or revocation of the pharmacy license of the pharmacy in which the intern has violated this section of the pharmacy law.

(3) The board may, upon notice and after a hearing, temporarily suspend or permanently revoke or refuse to renew any license of any registered pharmacist, or intern pharmacist, found to have been employed in any establishment which:

(a) does not have a license required by the pharmacy laws of the state of Montana, 37-7-321, MCA. (History: 37-7-201, MCA; IMP, 37-7-201, 37-7-311, 37-7-321, MCA; NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904.)